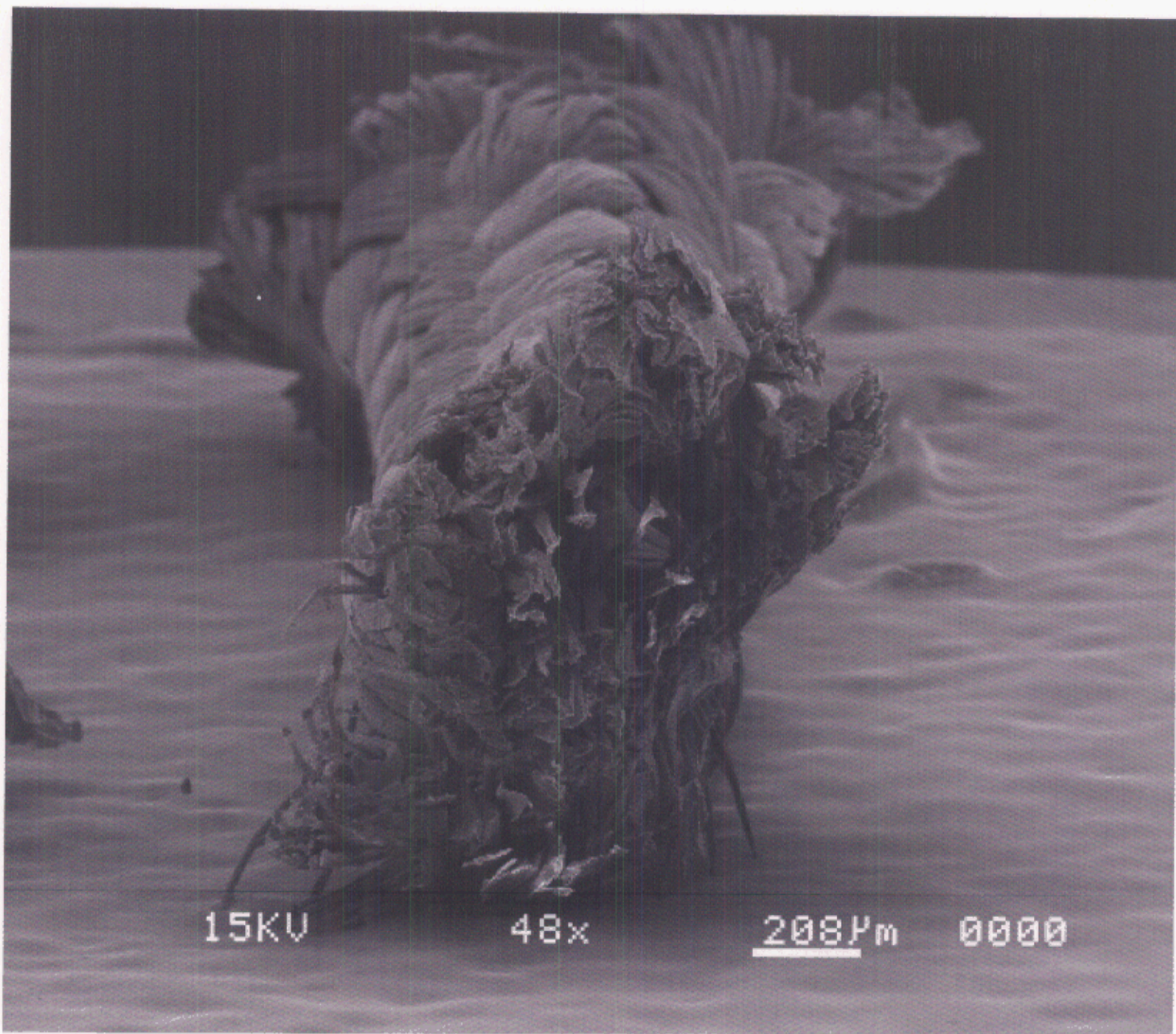


# **BROOKSTEIN DECLARATION EXHIBIT 22**



# **BROOKSTEIN DECLARATION EXHIBIT 23**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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DEPUY MITEK, INC., a  
Massachusetts Corporation,  
Plaintiff,  
:

Civil Action No.  
: 04-12457 PBS

-vs-

ARTHREX, INC., a Delaware  
Corporation, and PEARSALLS  
LTD., a Private Limited  
Company of the United  
Kingdom,  
:

: EXPERT DEPOSITION OF:  
: ROBERT T. BURKS, M.D.

Defendants.

-O-

Location: Marriott University Hotel  
Salt Lake City, Utah

Date: June 7, 2006  
3:00 p.m.

Reporter: Denise Kirk, CSR/RPR

-O-

| <p>1 APPEARANCES</p> <p>2 For the Plaintiff:</p> <p>3 ERICH M. FALKE and</p> <p>4 MICHAEL J. BONELLA</p> <p>5 WOODCOCK WASHBURN, LLP</p> <p>6 One Liberty Place - 46th Floor</p> <p>7 Philadelphia, PA 19103</p> <p>8 (215)564-8987</p> <p>9 (215)568-3439 (fax)</p> <p>10 Efalke@woodcock.com</p> <p>11</p> <p>12 For the Defendant:</p> <p>13 SALVATORE P. TAMBURIO</p> <p>14 DICKSTEIN SHAPIRO MORIN OSHINSKY</p> <p>15 2101 L Street NW</p> <p>16 Washington, DC 20037-1526</p> <p>17 (202)822-5164</p> <p>18 (202)887-0689 (fax)</p> <p>19 TamburoS@dsmo.com</p> <p>20 -O-</p> <p>21 INDEX</p> <p>22</p> <table border="1"> <thead> <tr> <th>Witness</th> <th>Page</th> </tr> </thead> <tbody> <tr> <td>ROBERT T. BURKS, M.D.</td> <td></td> </tr> <tr> <td>Examination by Mr. Falke</td> <td>4</td> </tr> <tr> <td>Examination by Mr. Tamburo</td> <td>99</td> </tr> <tr> <td>-O-</td> <td></td> </tr> </tbody> </table> <p>23</p> <p>24</p> <p>25</p> | Witness   | Page | ROBERT T. BURKS, M.D. |  | Examination by Mr. Falke | 4 | Examination by Mr. Tamburo | 99 | -O- |  | <p>1 June 7, 2006 3:05 p.m.</p> <p>2 PROCEEDINGS</p> <p>3 (Discussion off the record.)</p> <p>4 THE VIDEOGRAPHER: We are on record at</p> <p>5 3:05. This is the videotape deposition of Dr. Robert</p> <p>6 T. Burks taken on June 7, 2006 in the matter of DePuy</p> <p>7 Mitek, Incorporated, a Massachusetts corporation,</p> <p>8 versus Arthrex, Incorporated, a Delaware corporation.</p> <p>9 The case number is 04-12457 PBS in the</p> <p>10 United States District Court for the District of</p> <p>11 Massachusetts.</p> <p>12 My name is Donna Polton. I'm a licensed</p> <p>13 videographer. The court reporter is Denise Kirk. We</p> <p>14 represent the firm of Veritext Corporate Services.</p> <p>15 Counsel will now state their appearances</p> <p>16 for the record and the witness will be sworn in.</p> <p>17 MR. FALKE: Erich Falke and Michael</p> <p>18 Bonella from Woodcock Washburn representing plaintiff</p> <p>19 DePuy Mitek.</p> <p>20 MR. TAMBURIO: Salvatore Tamburo</p> <p>21 representing Arthrex Inc.</p> <p>22 ROBERT T. BURKS, M.D.</p> <p>23 Called as a witness herein, being</p> <p>24 First duly sworn was examined</p> <p>25 And testified as follows:</p> |
|--|---|------|-----------------------|--|--------------------------|---|----------------------------|----|-----|--|---|
| Witness  | Page  |      |                       |  |                          |   |                            |    |     |  |   |
| ROBERT T. BURKS, M.D.  |   |      |                       |  |                          |   |                            |    |     |  |   |
| Examination by Mr. Falke   | 4   |      |                       |  |                          |   |                            |    |     |  |   |
| Examination by Mr. Tamburo   | 99  |      |                       |  |                          |   |                            |    |     |  |   |
| -O-  |   |      |                       |  |                          |   |                            |    |     |  |   |
| <p>1 EXHIBITS</p> <p>2 (All Exhibits premarked by Mr. Falke)</p> <p>3 Number Description</p> <p>4 231 Subpoena in a Civil Case</p> <p>5 232 Expert Report of Robert Burks, M.D.</p> <p>6 233 Curriculum Vitae</p> <p>7 234 Chart of sutures</p> <p>8 235 Sutures retained by Mr. Falke</p> <p>9 236 Sutures retained by Mr. Falke</p> <p>10 237 Sutures retained by Mr. Falke</p> <p>11</p> <p>12 -O-</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>  | <p>1 EXAMINATION</p> <p>2 BY MR. FALKE:</p> <p>3 Q. Good afternoon, Dr. Burks. How are you?</p> <p>4 A. Good.</p> <p>5 Q. Have you ever been deposed before. Dr.</p> <p>6 Burks?</p> <p>7 A. Yes.</p> <p>8 Q. On how many occasions have you been</p> <p>9 deposed?</p> <p>10 A. Several. I don't know a number.</p> <p>11 Q. More than five?</p> <p>12 A. Yeah.</p> <p>13 Q. Less than ten?</p> <p>14 A. Reasonable.</p> <p>15 Q. I'm just going to go over a few of the</p> <p>16 ground rules to make sure we're on the same page.</p> <p>17 Periodically we'll be taking breaks, roughly once an</p> <p>18 hour. But if there's any time you feel you need to</p> <p>19 take a break, let us know and we'll accommodate you as</p> <p>20 soon as we can.</p> <p>21 Do you understand you've taken an oath to</p> <p>22 tell the truth today?</p> <p>23 A. Yes.</p> <p>24 Q. And that leads me to the next one. All</p> <p>25 answers, could you please make them verbal so that the</p> |      |                       |  |                          |   |                            |    |     |  |   |

2 (Pages 2 to 5)



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| <p>1 court reporter can transcribe them as opposed to<br/>2 shaking your head or nodding your head: do you<br/>3 understand that?<br/>4 A. Yes.<br/>5 Q. Also, if you'll allow me to finish the<br/>6 question before you answer, it will make for a better<br/>7 transcript. Even though you may even be able to<br/>8 anticipate the end of my question by what I say in the<br/>9 beginning, if you'd allow me to finish and then answer<br/>10 it will allow the reporter to make a clear transcript;<br/>11 do you understand that?<br/>12 A. I do.<br/>13 Q. Also, if I ask you a question and you<br/>14 don't understand, I'll ask that you tell me you don't<br/>15 understand the question. Otherwise, I'll assume that<br/>16 you did understand the question; is that fair?<br/>17 A. Fair.<br/>18 Q. Are you being represented today by<br/>19 counsel?<br/>20 A. Yes.<br/>21 Q. Who is your counsel?<br/>22 A. Sal Tamburo.<br/>23 Q. Do you know when Sal or the law firm<br/>24 Dickstein Shapiro Morin &amp; Oshinsky began representing<br/>25 you for purposes of this case?</p> | <p>1 A. Yes.<br/>2 Q. What is Exhibit Number 231?<br/>3 A. A subpoena for me.<br/>4 Q. Did you understand that be Exhibit 231 was<br/>5 a subpoena on you for certain documents and things<br/>6 listed in schedule A of Exhibit 231?<br/>7 A. Yes.<br/>8 Q. Today are you producing any documents or<br/>9 things in response to the subpoena. Exhibit 231?<br/>10 A. No.<br/>11 Q. If you could turn to page two of Exhibit<br/>12 Number 231, please. Do you see request number one for<br/>13 documents there, being all communications between any<br/>14 of Arthrex, you, Dr. Mukherjee and Dickstein Shapiro<br/>15 Morin &amp; Oshinsky concerning the lawsuit commenced by<br/>16 the plaintiff attached as Exhibit 1?<br/>17 A. Yes.<br/>18 Q. Did you perform any search that might be<br/>19 responsive to request number one in Exhibit Number<br/>20 231?<br/>21 A. Yes.<br/>22 Q. Did you find any?<br/>23 A. No.<br/>24 Q. Request number two in Exhibit 231 is all<br/>25 documents concerning this lawsuit, including, but not</p>   |
| <p>1 A. In February.<br/>2 Q. Is that when Arthrex or Dickstein<br/>3 contacted you with respect to your role in this case?<br/>4 A. Yes.<br/>5 Q. Are you being compensated for the time you<br/>6 spend on this lawsuit?<br/>7 A. Yes.<br/>8 Q. How are you being compensated?<br/>9 A. How much?<br/>10 Q. Yes.<br/>11 A. \$400 an hour.<br/>12 Q. Was that a negotiated fee or was that your<br/>13 standard fee for doing expert consulting?<br/>14 A. I don't really have a standard fee, so I<br/>15 guess you could call it negotiated.<br/>16 Q. Other than money, is there any other<br/>17 compensation you are receiving for work on this case?<br/>18 A. No.<br/>19 Q. Were you given any dollar amount that you<br/>20 should not exceed in performing work for Arthrex in<br/>21 this case?<br/>22 A. No.<br/>23 Q. I'm going to hand you DePuy Mitek Exhibit<br/>24 231 and ask you if you recognize this document,<br/>25 Exhibit 231?</p>   | <p>1 limited -- well, hold on. Strike that.<br/>2 Did you perform a reasonable search for<br/>3 documents in response to request number two in<br/>4 Schedule A of Exhibit 231?<br/>5 A. I guess I don't see the difference. There<br/>6 aren't any documents that I'm aware of in the lawsuit.<br/>7 Q. Under things to be produced on page two of<br/>8 Exhibit Number 231, request number one is all tested<br/>9 and untested samples referred to in Expert Report of<br/>10 Robert T. Burks, MD dated March 24, 2006, including,<br/>11 but not limited to suture A and suture B. Do you see<br/>12 that?<br/>13 A. I do.<br/>14 Q. Did you perform a search for things<br/>15 responsive to request number one?<br/>16 A. No.<br/>17 Q. You did not?<br/>18 A. I knew it didn't exist.<br/>19 Q. You knew what didn't exist?<br/>20 A. The suture.<br/>21 Q. You mean the tested and untested samples?<br/>22 A. The pieces that I had I had disposed of<br/>23 when I was done. I knew there wasn't anything to look<br/>24 for.<br/>25 Q. Under request number two on things to be</p> |

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| <p>10</p> <p>1 produced on page two of Exhibit 231 is all equipment<br/>2 used to test the samples as described in paragraphs<br/>3 nine through 13 of Expert Report of Robert T. Burks,<br/>4 MD dated March 24, 2006, including, but not limited to<br/>5 the equipment that was used to cut and wet the samples<br/>6 and to conduct the tactile feel analysis and knot<br/>7 tie-down analysis; do you see that?<br/>8 A. I do.<br/>9 Q. Did you perform a search for the materials<br/>10 requested in request number 2?<br/>11 A. No.<br/>12 Q. Why not?<br/>13 A. The equipment that was used was a pair of<br/>14 scissors just to cut it, something from home, I felt<br/>15 like it didn't have relevance.<br/>16 Q. What about the solution that was used to<br/>17 wet these tested samples?<br/>18 A. I used tap water.<br/>19 Q. Did you use anything else in performing<br/>20 the tests described in paragraphs nine through 13 of<br/>21 your expert report other than tap water and scissors<br/>22 and the sutures?<br/>23 MR. TAMBURRO: It might help if the witness<br/>24 had his report in front of him to refer to.<br/>25 A. The things used, like a pair of gloves,</p> | <p>12</p> <p>1 Q. What about medical school?<br/>2 A. '78.<br/>3 Q. Then, after medical school, where did you<br/>4 go?<br/>5 A. To residency training.<br/>6 Q. When did you finish your residency<br/>7 training?<br/>8 A. '83.<br/>9 Q. Where was your residency training?<br/>10 A. University of California San Diego.<br/>11 Q. Did you have a specialty there?<br/>12 A. Yes. Well, there's no specialty in<br/>13 training per se, but I did do a fellowship during that<br/>14 time with Dale Daniel at Kaiser Permanente.<br/>15 Q. What was that fellowship in?<br/>16 A. Knee and sports medicine.<br/>17 Q. When did you finish your fellowship in<br/>18 knee and sports medicine?<br/>19 A. '83.<br/>20 Q. Other than those programs or degrees you<br/>21 mentioned, are there any other -- is there any other<br/>22 formal education that you've gone through?<br/>23 A. No.<br/>24 Q. Once you completed your fellowship in knee<br/>25 and sports medicine in 1983, what did you do?</p>   |
| <p>11</p> <p>1 are disposed of after and they're just a generic set.<br/>2 There wasn't anything used that would be unique that I<br/>3 felt would be worthwhile to produce.<br/>4 Q. So you used gloves when you performed the<br/>5 tactile feel analysis and knot tie-down analysis?<br/>6 A. I did both. I used and didn't use gloves.<br/>7 Q. Is there any reason why you decided not to<br/>8 bring gloves today?<br/>9 A. No.<br/>10 Q. Did your counsel advise you to bring<br/>11 gloves?<br/>12 A. No.<br/>13 Q. Did you go over -- did you have a chance<br/>14 to go over Exhibit 231 with your counsel before coming<br/>15 to today's deposition?<br/>16 A. Yes, we looked at it.<br/>17 Q. Dr. Burks, could you please describe your<br/>18 formal education post-high school for me, please.<br/>19 A. I did medical school at St. Louis<br/>20 university. I guess after high school I did college<br/>21 at Southern Methodist University, medical school at<br/>22 St. Louis university, orthopedic training at<br/>23 University of California San Diego.<br/>24 Q. When did you graduate from undergrad?<br/>25 A. Undergrad college was '74.</p>                           | <p>13</p> <p>1 A. I went into private practice in St. Louis,<br/>2 Missouri.<br/>3 Q. What was the focus of your private<br/>4 practice in St. Louis?<br/>5 A. Sports medicine, general orthopedics.<br/>6 Q. Did you focus on any particular parts of<br/>7 the body within sports medicine and general<br/>8 orthopedics?<br/>9 A. Knee and shoulder were the big focus.<br/>10 Q. And when did you leave private practice in<br/>11 St. Louis?<br/>12 A. I was there three years; I believe it was<br/>13 '86.<br/>14 Q. Then what did you do in 1986?<br/>15 A. I went to Wayne State University in<br/>16 Detroit.<br/>17 Q. What did you do at Wayne State?<br/>18 A. I was on the academic staff there and was<br/>19 the head of sports medicine.<br/>20 Q. Your time spent at Wayne State, was that<br/>21 strictly in an academic environment or did that also<br/>22 include a clinical practice?<br/>23 A. Yes. I mean, it was a clinical practice,<br/>24 but it was as a full-time faculty member.<br/>25 Q. Can you explain how that works, your role</p> |

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| <p>14</p> <p>1 at Wayne State, how it was spent between full-time<br/>2 faculty member and participating in a clinical<br/>3 practice?</p> <p>4 A. Well, there's really no distinction. I<br/>5 mean, my job was to take care of patients and people.<br/>6 And so the education was for residents and that's what<br/>7 they were training to do was take care of people.<br/>8 So there really wasn't a distinction<br/>9 between a clinical practice and what you are doing<br/>10 academically as far as your work goes.</p> <p>11 Q. So did you teach in a classroom setting?</p> <p>12 A. No.</p> <p>13 Q. So I think I understand. What type of<br/>14 medicine did you practice at Wayne State as a<br/>15 full-time faculty member and in a clinical practice?</p> <p>16 A. It was orthopedic surgery with an emphasis<br/>17 in sports medicine.</p> <p>18 Q. Again, did you focus on the knee and<br/>19 shoulder areas?</p> <p>20 A. Yes.</p> <p>21 Q. When you were at Wayne State what were the<br/>22 -- generally what were the procedures that you would<br/>23 perform for shoulder surgeries?</p> <p>24 A. Perform shoulder instability operations,<br/>25 rotator cuff operations, things that we do for what we</p> | <p>16</p> <p>1 Q. In 1988 after leaving Wayne State, what<br/>2 did you do?</p> <p>3 A. I came here to the University of Utah.</p> <p>4 Q. What position did you enter the University<br/>5 of Utah in 1988?</p> <p>6 A. I was an assistant professor in orthopedic<br/>7 surgery. And we didn't really have a true division,<br/>8 but I was part of the sports medicine team.</p> <p>9 Q. Can you generally describe your duties as<br/>10 an assistant professor in the orthopedic surgery<br/>11 department at the University of Utah?</p> <p>12 A. Duties were to take care of standard<br/>13 patients that we would see, to instruct residents in<br/>14 clinical evaluation of patients and surgical treatment<br/>15 of patients, to be involved in some areas of research<br/>16 and produce academically, and were involved with<br/>17 taking care of the athletic teams.</p> <p>18 Q. While at the University of Utah, I take it<br/>19 from 1988 to the present you've remained at the<br/>20 University of Utah?</p> <p>21 A. Yes.</p> <p>22 Q. From 1988 to the present, do you perform<br/>23 any classroom teaching?</p> <p>24 A. Minimally. Occasionally it comes up, but<br/>25 not very much.</p> |
| <p>15</p> <p>1 call impingement, shoulder pain procedures, procedures<br/>2 that revolve around the clavicle.</p> <p>3 Q. Anything else you can think of?</p> <p>4 A. I mean, it's a pretty wide area, but those<br/>5 are the main things.</p> <p>6 Q. What about when you were at Wayne State,<br/>7 what were the procedures that you would perform for<br/>8 knee surgeries?</p> <p>9 A. Ligament reconstructions, operations for<br/>10 instability of the knee cap, cartilage procedures,<br/>11 meniscus procedures.</p> <p>12 Q. When you were at Wayne State, did you<br/>13 perform any ankle surgeries?</p> <p>14 A. Sure.</p> <p>15 Q. What ankle surgeries? What procedures<br/>16 would you perform doing ankle surgeries?</p> <p>17 A. The main procedures revolved around<br/>18 arthroscopy, and then I would do some procedures that<br/>19 revolved around loose ankle joints where people have<br/>20 chronic ankle sprains and tightening those up.</p> <p>21 Q. Then, I take it, at some point you left<br/>22 Wayne State?</p> <p>23 A. Correct.</p> <p>24 Q. What year was that?</p> <p>25 A. '88.</p>   | <p>17</p> <p>1 Q. What classes would you teach when it comes<br/>2 up?</p> <p>3 A. It's usually just an isolated lecture, not<br/>4 like a class series. So it would be lectures to the<br/>5 residents or to medical students on a specific topic,<br/>6 sometimes to physical therapy students.</p> <p>7 Q. Since 1988, how have your duties and<br/>8 responsibilities at the University of Utah changed?</p> <p>9 A. I don't think they've changed much.</p> <p>10 Q. Okay. At some point you did become head<br/>11 of the sports medicine division, though, right?</p> <p>12 A. Correct.</p> <p>13 Q. Do you know when that happened?</p> <p>14 A. I'd be guessing a little. I'm not sure of<br/>15 the exact year.</p> <p>16 Q. How about 1992, does that sound familiar?</p> <p>17 A. That's probably close.</p> <p>18 Q. Dr. Burks, I'm going to hand you Exhibit<br/>19 Number 233. This is a printout of a web page from the<br/>20 University of Utah. If you could just please look at<br/>21 that.</p> <p>22 MR. TAMBURO: Do you have another copy?</p> <p>23 Q. No. Just let me know if that's generally<br/>24 accurate.</p> <p>25 A. Yes.</p>   |



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| <p style="text-align: right;">18</p> <p>1 Q. Dr. Burks, can you describe for me your<br/>2 relationship with Arthrex, Inc.?</p> <p>3 MR. TAMBURIO: Objection, vague.</p> <p>4 A. I am a consumer. Over the years I have<br/>5 been an advisor for different products. That's it.</p> <p>6 Q. You say you are a consumer of Arthrex<br/>7 products. What Arthrex products do you use?</p> <p>8 A. Well, we use things like drill guides, use<br/>9 suture anchors and sutures, drill bits. That's it.</p> <p>10 Q. Do you use any Arthrex knee fixation<br/>11 devices?</p> <p>12 A. I have used Arthrex knee fixation devices<br/>13 but don't currently use any.</p> <p>14 Q. What did you use?</p> <p>15 A. They have an interference screw that is<br/>16 metal and one that is absorbable that I used to use<br/>17 that I don't use now.</p> <p>18 Q. Earlier you said things like we used<br/>19 things like drill guides, suture anchors, and sutures,<br/>20 drill bits. Who were you referring to when you said<br/>21 "we"?</p> <p>22 A. I guess it was the generic "we" of the<br/>23 sports medicine service.</p> <p>24 Q. Do you personally use those Arthrex<br/>25 products?</p>  | <p style="text-align: right;">20</p> <p>1 Q. Other than royalties and other than money<br/>2 for your work you've performed in this lawsuit, do you<br/>3 receive any other money from Arthrex?</p> <p>4 A. No.</p> <p>5 Q. How many different pieces of Arthrex<br/>6 equipment to you receive royalties on?</p> <p>7 A. There is a knee ligament guide system that<br/>8 has a few different pieces in it. So I can't give an<br/>9 exact number. It's sort of a guide system with four<br/>10 or five different pieces, parts of it.</p> <p>11 There is a screw that we use for<br/>12 augmenting ligament fixation that I get some royalties<br/>13 on along with those guides.</p> <p>14 Q. Do you know what the trade name is for the<br/>15 knee ligament guides that you receive royalties from<br/>16 Arthrex on?</p> <p>17 A. It's kind of silly that I wouldn't be able<br/>18 to give you that. It's for posterior cruciate<br/>19 ligament reconstruction.</p> <p>20 Q. And do you know what the trade name is on<br/>21 the screw that you receive royalties from Arthrex on?</p> <p>22 A. I don't.</p> <p>23 Q. For what area of the body is this screw<br/>24 used on?</p> <p>25 A. It could be used anywhere, but I think the</p> |
| <p style="text-align: right;">19</p> <p>1 A. Oh, yes.</p> <p>2 Q. Do you have any consulting agreements with<br/>3 Arthrex?</p> <p>4 A. To be honest, I'm not sure of the direct<br/>5 answer to give you on that. I have a couple of pieces<br/>6 of equipment that I have worked with them on in<br/>7 developing, so that might be considered a consulting<br/>8 agreement.</p> <p>9 I'm not a consultant, just a generic like<br/>10 on a board of advisors or something like that.</p> <p>11 Q. I don't understand when you say "I have a<br/>12 couple of pieces of equipment I worked with them on in<br/>13 developing so that might be considered a consulting<br/>14 agreement", could you explain that?</p> <p>15 A. Well, I went to them to develop a guide<br/>16 for a knee ligament reconstruction. They liked the<br/>17 idea. They made the guide. They have the guide as one<br/>18 of the products that they sell, and then I get some<br/>19 royalty from their sales.</p> <p>20 Q. Okay. So other than services you performed<br/>21 for this case, have you received money from Arthrex<br/>22 for other services such as, for example, this work you<br/>23 did with the guide?</p> <p>24 A. I think I just said I get royalties for<br/>25 that.</p> | <p style="text-align: right;">21</p> <p>1 large majority would be at the knee.</p> <p>2 Q. Are you the named inventor on any patents?</p> <p>3 A. No.</p> <p>4 Q. The screw that you developed with Arthrex,<br/>5 is that used for the ACL or PCL?</p> <p>6 A. Can be either.</p> <p>7 Q. Is that an interference screw?</p> <p>8 A. No. It's a screw we typically refer to as<br/>9 a post. And what that means is that suture from a<br/>10 ligament or tendon gets tied around this to help hold<br/>11 it while it's healing in.</p> <p>12 Q. You also said, in describing your<br/>13 relationship with Arthrex, you used the word<br/>14 "advisor". We've just been talking about you<br/>15 developing certain equipment. Is that what you meant<br/>16 by advisor?</p> <p>17 A. Yes.</p> <p>18 Q. Do you advise Arthrex in any other way<br/>19 other than what we've just talked about with respect<br/>20 to developing equipment?</p> <p>21 A. No.</p> <p>22 Q. Do you know Dr. Paul Fenton from Toledo,<br/>23 Ohio?</p> <p>24 A. I don't.</p> <p>25 Q. What about Dr. Marlow Goebel?</p>   |

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| <p style="text-align: right;">22</p> <p>1 A. I do.</p> <p>2 Q. How do you know Dr. Goebel?</p> <p>3 A. Dr. Goebel practices in Logan, and is an</p> <p>4 adjunct faculty here at the University. So I've known</p> <p>5 him pretty much since I came here in '88.</p> <p>6 Q. Does Dr. Goebel have a reputation in the</p> <p>7 field?</p> <p>8 A. Sure.</p> <p>9 Q. Do you know that reputation is?</p> <p>10 A. Well, I know my perception of his</p> <p>11 reputation. I think he is a very inventive,</p> <p>12 unique-thinking orthopedic surgeon who has focused his</p> <p>13 career on knee surgery.</p> <p>14 Q. What about Dr. Richard Greenwald, not a</p> <p>15 medical doctor, but I believe he's a PhD?</p> <p>16 A. No.</p> <p>17 Q. Generally speaking, how much in royalties</p> <p>18 have you received from Arthrex for your work in</p> <p>19 developing the equipment that we've just talked about?</p> <p>20 A. I couldn't give you an exact number, but I</p> <p>21 would say the royalties in a given year probably</p> <p>22 fluctuate between seven and ten or \$11,000.</p> <p>23 Q. Have you ever been to Naples, Florida to</p> <p>24 visit Arthrex?</p> <p>25 A. Yes.</p>            | <p style="text-align: right;">24</p> <p>1 Q. When you went to Arthrex, who paid for the</p> <p>2 visits?</p> <p>3 A. The meeting that was held was paid for by</p> <p>4 Arthrex. The other visit, I don't honestly remember</p> <p>5 how I got down there.</p> <p>6 Q. The first time you went to Arthrex, how</p> <p>7 many days did you stay down in Naples?</p> <p>8 A. I'm going to say two.</p> <p>9 Q. The second time?</p> <p>10 A. Two to two and-a-half.</p> <p>11 Q. Other than a consumer and advisor, how</p> <p>12 else would you describe your relationship with</p> <p>13 Arthrex?</p> <p>14 A. I've known the president of the company</p> <p>15 since near the beginning of the development of the</p> <p>16 company. So I've had interactions suggesting things</p> <p>17 that might be beneficial to look at or might improve</p> <p>18 patient care in certain circumstances. I've had that</p> <p>19 kind of relationship, I think.</p> <p>20 Q. Anything else?</p> <p>21 A. No.</p> <p>22 Q. How long have you been a consumer of</p> <p>23 Arthrex products?</p> <p>24 A. Well, from pretty much when they got</p> <p>25 rolling, which I don't remember exactly, I'm going to</p> |
| <p style="text-align: right;">23</p> <p>1 Q. On how many occasions have you gone to</p> <p>2 Naples to visit Arthrex?</p> <p>3 A. I believe twice.</p> <p>4 Q. What did you do when you went to Arthrex?</p> <p>5 A. One of the visits was a meeting which had</p> <p>6 orthopedic surgeons from the United States and Europe</p> <p>7 and some South America. And it was an academic</p> <p>8 meeting but, obviously, focused on Arthrex things.</p> <p>9 One time was just as they had opened their</p> <p>10 new manufacturing plants and facilities and it was to</p> <p>11 tour and visit.</p> <p>12 Q. When was the first time you were at</p> <p>13 Arthrex?</p> <p>14 A. I'd be guessing. I'm going to say maybe</p> <p>15 six years ago.</p> <p>16 Q. When was the second time you visited</p> <p>17 Arthrex?</p> <p>18 A. About two or three years ago.</p> <p>19 Q. How many years have you been receiving</p> <p>20 royalties from Arthrex on the knee ligament guide?</p> <p>21 A. I don't know for sure. I'm going to say</p> <p>22 five.</p> <p>23 Q. How many years have you been receiving</p> <p>24 royalties from Arthrex on the screw?</p> <p>25 A. Probably similar, maybe a year longer.</p> | <p style="text-align: right;">25</p> <p>1 say like 1990, but I don't know for sure.</p> <p>2 Q. Would you say you use more Arthrex</p> <p>3 products now than you did ten years ago?</p> <p>4 A. Certainly.</p> <p>5 Q. Why is that?</p> <p>6 A. They have more products now than they did</p> <p>7 ten years ago.</p> <p>8 Q. Any other reason?</p> <p>9 A. I like the products.</p> <p>10 Q. Anything else?</p> <p>11 A. No.</p> <p>12 Q. Dr. Burks, I'm going to hand you DePuy</p> <p>13 Mitek Exhibit 232. Could you identify Exhibit 232 for</p> <p>14 me please?</p> <p>15 A. 232 is my report to Sal Tamburo and my CV.</p> <p>16 Q. Did you write Exhibit Number 232?</p> <p>17 A. Well, I certainly had a hand in writing</p> <p>18 the CV. The other part of the report was written after</p> <p>19 conversation with Sal, by Sal.</p> <p>20 Q. So you talked to Sal and then Sal wrote</p> <p>21 the report and then did you sign it after it was</p> <p>22 written by Sal?</p> <p>23 A. Sal and I talked about the report, he</p> <p>24 wrote it, I reviewed it, had to make some changes here</p> <p>25 and there on background and what not, and then</p>                                  |

7 (Pages 22 to 25)

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| <p>26</p> <p>1 conversed with him about that and then signed the<br/>2 final.<br/>3 Q. What changes did you make to the report<br/>4 after Sal initially drafted it?<br/>5 A. I don't remember specifics, but I think<br/>6 some of the background of when I did this or where I<br/>7 was or something hadn't been finished, but I don't<br/>8 remember the other specific changes.<br/>9 Q. Do you know if there are any drafts of<br/>10 Exhibit 232?<br/>11 A. I don't have any.<br/>12 Q. Do you know if any exist?<br/>13 A. I don't know.<br/>14 Q. How was the initial draft prepared by Sal<br/>15 sent to you?<br/>16 A. E-mail.<br/>17 Q. E-mail?<br/>18 A. Yes.<br/>19 Q. And then what did you do with the e-mail?<br/>20 A. Made a few changes and -- to be perfectly<br/>21 honest, I can't remember if I made changes and sent<br/>22 them back or got on the phone and said, hey, here's<br/>23 where I would fill in this or change that. I don't<br/>24 remember.<br/>25 Q. Do you remember physically or</p>                     | <p>28</p> <p>1 Q. Let me ask you the question again. Do you<br/>2 remember when you signed the report. Exhibit 232?<br/>3 A. I will say March 24, 2006.<br/>4 Q. Do you remember what time of day you<br/>5 signed Exhibit Number 232?<br/>6 A. No.<br/>7 Q. Do you remember where you were when you<br/>8 signed Exhibit 232?<br/>9 A. I'm sure I was somewhere in my office.<br/>10 Q. Once you signed Exhibit 232, did you fax<br/>11 it back to Sal?<br/>12 A. I don't remember.<br/>13 Q. Do you remember signing it in the morning?<br/>14 A. I don't remember.<br/>15 Q. Do you remember signing it in the<br/>16 afternoon?<br/>17 A. No, I don't remember that.<br/>18 Q. Do you remember signing it at night?<br/>19 A. I don't. It wasn't a huge event in my life<br/>20 so I...<br/>21 Q. So once it was signed, do you remember how<br/>22 it was communicated back to Sal? Was it faxed or was<br/>23 it overnighted?<br/>24 A. To be honest, I don't remember.<br/>25 Q. In the course of preparing the report, did</p> |
| <p>27</p> <p>1 electronically changing the word document and sending<br/>2 it back to Sal?<br/>3 A. I don't remember doing that.<br/>4 Q. Do you remember printing it out?<br/>5 A. I don't.<br/>6 Q. Do you remember if you read it on the<br/>7 screen or did you read it in hard copy form?<br/>8 A. I certainly read it on the screen. I can't<br/>9 remember if I made changes based on what was on the<br/>10 screen or if I just got on the phone and the changes<br/>11 were made then.<br/>12 Q. But you are pretty sure you didn't print<br/>13 it out and make handwritten comments on it?<br/>14 A. Right, right. Yes.<br/>15 Q. Let me ask you a better question: Did you<br/>16 print out the e-mail that Sal sent you of the initial<br/>17 draft of the report and then make handwritten comments<br/>18 on it?<br/>19 A. No.<br/>20 Q. Do you remember when you signed the<br/>21 report?<br/>22 A. Without looking at any data on it, I don't<br/>23 have a specific.<br/>24 Q. Feel free to look at the data.<br/>25 A. Okay.</p> | <p>29</p> <p>1 you review any documents concerning this case?<br/>2 A. No.<br/>3 Q. Other than Sal, did you speak with anybody<br/>4 else about the preparation of Exhibit 232?<br/>5 A. No.<br/>6 Q. Did you speak to Dr. Mukherjee with<br/>7 respect to preparing Exhibit Number 232?<br/>8 A. No.<br/>9 Q. Did you speak to any Arthrex employee in<br/>10 preparing Exhibit 232?<br/>11 A. No.<br/>12 Q. With respect to this present case, have<br/>13 you ever spoken to Dr. Mukherjee?<br/>14 A. No.<br/>15 Q. With respect to this present case, have<br/>16 you ever had any communications with Dr. Mukherjee?<br/>17 A. No.<br/>18 Q. No e-mails?<br/>19 A. I don't know Dr. Mukherjee.<br/>20 Q. How did you prepare for today's<br/>21 deposition, Dr. Burks?<br/>22 A. I had a meeting with Sal Tamburo.<br/>23 Q. Anything else?<br/>24 A. No.<br/>25 Q. When did you meet with Sal Tamburo for</p>  |

8 (Pages 26 to 29)

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| <p>30</p> <p>1 preparation of today's deposition?</p> <p>2 A. Last night.</p> <p>3 Q. Where did you meet?</p> <p>4 A. Here.</p> <p>5 Q. At the hotel?</p> <p>6 A. Yes.</p> <p>7 Q. For about how long did you meet with Sal</p> <p>8 in preparation for today's deposition?</p> <p>9 A. Two hours.</p> <p>10 Q. Did you have a chance to speak with Mr.</p> <p>11 Tamburo today about preparing for today's deposition?</p> <p>12 A. No.</p> <p>13 Q. When you met with Mr. Tamburo last night</p> <p>14 for about two hours, what did you discuss?</p> <p>15 A. We talked about the report, talked about</p> <p>16 basics on depositions, that it would be a video</p> <p>17 deposition, etc. I can't remember, really, any other</p> <p>18 specifics.</p> <p>19 Q. What did you talk about when you talked</p> <p>20 about the report?</p> <p>21 A. I think it was more just what probably</p> <p>22 would be the basis of questions, i.e., background,</p> <p>23 questions of, you know, how things were done,</p> <p>24 questions of relationships, things like that.</p> <p>25 Q. When you say "how things were done", what</p>   | <p>32</p> <p>1 where it needs to be visible.</p> <p>2 Q. Continue.</p> <p>3 A. What else would be important to me? Size</p> <p>4 of the suture is important, obviously.</p> <p>5 Q. I'm sorry, just so we're on the same page.</p> <p>6 my question was not directed to what's important to</p> <p>7 you but what's important to an orthopedic surgeon as</p> <p>8 written in paragraph six of your report. Exhibit 232.</p> <p>9 A. Okay. I'm an orthopedic surgeon so I was</p> <p>10 thinking what would be important to me and what would</p> <p>11 be important to other orthopedic surgeons.</p> <p>12 Q. Okay. So what you wrote in Exhibit 232,</p> <p>13 paragraph six, the first sentence, it says: "I may</p> <p>14 describe the characteristics of a surgical suture that</p> <p>15 are generally important to an orthopedic surgeon."</p> <p>16 When you say "to an orthopedic surgeon"</p> <p>17 there, are you referring to a generic orthopedic</p> <p>18 surgeon or are you referring to yourself?</p> <p>19 A. I would say my opinion of those</p> <p>20 characteristics for an orthopedic surgeon, of which I</p> <p>21 am one.</p> <p>22 Q. So those characteristics are generally</p> <p>23 important to you or to another orthopedic surgeon?</p> <p>24 A. I think both.</p> <p>25 Q. Because there's some things that you might</p>    |
| <p>31</p> <p>1 are you referring to?</p> <p>2 A. Just methods of looking at the suture.</p> <p>3 Q. And how you performed the tests?</p> <p>4 A. Uh-huh.</p> <p>5 Q. Dr. Burks, could you please turn to</p> <p>6 paragraph six in Exhibit 232. Are you there?</p> <p>7 A. Yes.</p> <p>8 Q. Can you please describe the</p> <p>9 characteristics of a surgical suture that are</p> <p>10 generally important to an orthopedic surgeon?</p> <p>11 A. I think importance would be that it's</p> <p>12 compatible with the body so that there aren't</p> <p>13 significant reactions, strength.</p> <p>14 Q. You mean biological reactions?</p> <p>15 A. Yes. Strength of the suture is important,</p> <p>16 how a suture handles, passes through tissue and ties</p> <p>17 is important.</p> <p>18 Q. Anything else?</p> <p>19 A. Probably hundreds, but that will cover it.</p> <p>20 Q. Other than compatible with the body,</p> <p>21 strength, handles well and passes through the tissue,</p> <p>22 sitting here right now can you tell me any other</p> <p>23 characteristics of a surgical suture that are</p> <p>24 generally important to an orthopedic surgeon?</p> <p>25 A. Sure. There are certain circumstances</p> | <p>33</p> <p>1 consider important but another orthopedic surgeon</p> <p>2 might not consider important, is that right?</p> <p>3 A. That would be true.</p> <p>4 Q. So then in first sentence of paragraph</p> <p>5 six -- I'm still trying to understand -- you may</p> <p>6 describe characteristics of a surgical suture that are</p> <p>7 generally important to you or to another orthopedic</p> <p>8 surgeon?</p> <p>9 A. I would describe what my experience would</p> <p>10 tell me that most orthopedic surgeons feel is</p> <p>11 important and what I also feel.</p> <p>12 Q. Now, when you say "my experience would</p> <p>13 tell me that most orthopedic surgeons feel", what is</p> <p>14 that experience based on?</p> <p>15 A. It's based on over 25 years of doing this.</p> <p>16 Q. Okay. Is that experience based on any</p> <p>17 surveys you've read or conversations you've had with</p> <p>18 other orthopedic surgeons where they've told you that</p> <p>19 they think these particular characteristics of a</p> <p>20 surgical suture are important?</p> <p>21 A. I don't know that I could specifically</p> <p>22 relate to surveys but, certainly, there are</p> <p>23 conversations and discussions about it.</p> <p>24 Q. Have you read any surveys describing the</p> <p>25 characteristics of a surgical suture that are</p> |

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| <p>34</p> <p>1 generally important to an orthopedic surgeon?</p> <p>2 A. Not that I remember.</p> <p>3 Q. Have you conducted any surveys describing</p> <p>4 the characteristics of a surgical suture that are</p> <p>5 generally important to orthopedic surgeons?</p> <p>6 A. No.</p> <p>7 Q. Other than compatibility with the body,</p> <p>8 strength, handling, passing through tissue and size,</p> <p>9 are there any other characteristics of a surgical</p> <p>10 suture that are generally important to an orthopedic</p> <p>11 surgeon?</p> <p>12 A. I also mentioned knot tying.</p> <p>13 Q. Is knot security an important</p> <p>14 characteristic of a surgical suture?</p> <p>15 A. Sure.</p> <p>16 Q. Why is that?</p> <p>17 A. Well, if you tie a knot you intend to have</p> <p>18 a suture have a certain amount of tension in it and if</p> <p>19 you don't have knot security, you probably won't have</p> <p>20 that tension.</p> <p>21 Q. Anything else?</p> <p>22 A. No.</p> <p>23 Q. Is knot strength an important</p> <p>24 characteristic of a surgical suture?</p> <p>25 A. Sure.</p>          | <p>36</p> <p>1 A. Sure.</p> <p>2 MR. TAMBURRO: Objection: considered by Dr.</p> <p>3 Burks or who?</p> <p>4 Q. I think he can only testify for himself.</p> <p>5 So based on your opinion, the answer is the same?</p> <p>6 A. Sure.</p> <p>7 Q. All things being equal, a suture that has</p> <p>8 a lower knot profile would be considered advantageous</p> <p>9 over a suture that had a higher knot profile, is that</p> <p>10 generally correct?</p> <p>11 A. If one were to say all other things are</p> <p>12 equal, then sure.</p> <p>13 Q. Based on your experience in orthopedic</p> <p>14 surgery is it better to have fewer knots in a suture</p> <p>15 when performing surgery?</p> <p>16 A. You might have to work on that one again.</p> <p>17 I was just going to get a clarification of the</p> <p>18 question.</p> <p>19 Q. We'll come back to that one. You said</p> <p>20 strength is an important characteristic of a surgical</p> <p>21 suture; why is that?</p> <p>22 A. If the suture breaks, it doesn't do you</p> <p>23 any good.</p> <p>24 Q. Anything else?</p> <p>25 A. No.</p>  |
| <p>35</p> <p>1 Q. Why?</p> <p>2 A. Same.</p> <p>3 Q. Same as what?</p> <p>4 A. Same as what I just said.</p> <p>5 Q. Do you know what the term "knot profile"</p> <p>6 means?</p> <p>7 A. I think I do.</p> <p>8 Q. What's your understanding of the term knot</p> <p>9 profile?</p> <p>10 A. My understanding would be after a knot is</p> <p>11 tied, the suture frequently is wrapped around itself.</p> <p>12 And knot profile would be how large that knot</p> <p>13 generally appears after the knot has been tied and</p> <p>14 cut.</p> <p>15 Q. Is knot profile and knot height considered</p> <p>16 the same thing, based on your experience?</p> <p>17 A. I suppose they could be fairly close.</p> <p>18 Q. Is knot height and knot profile an</p> <p>19 important characteristic of a surgical suture?</p> <p>20 A. I think it would be fairly low on the</p> <p>21 grade if you were to mark it.</p> <p>22 Q. Is it considered an important</p> <p>23 characteristic of a surgical suture? Is knot height</p> <p>24 and knot profile considered important characteristics</p> <p>25 of a surgical suture?</p> | <p>37</p> <p>1 Q. You also said that handling is an</p> <p>2 important characteristic of a surgical suture?</p> <p>3 A. Sure.</p> <p>4 Q. Why is that?</p> <p>5 A. If you imagine trying to sew a suture</p> <p>6 together with a lead wire, it would make it much more</p> <p>7 difficult. So having flexibility and maneuvering is</p> <p>8 important.</p> <p>9 Q. As you use the term "handling", what are</p> <p>10 you referring to?</p> <p>11 A. The ability to manipulate a suture, to</p> <p>12 place a suture where you would like it to be, to be</p> <p>13 able to pull it together to tie knots.</p> <p>14 Q. Anything else?</p> <p>15 A. No.</p> <p>16 Q. You also said that passing through tissue</p> <p>17 is considered an important characteristic of a</p> <p>18 surgical suture. Why is that?</p> <p>19 A. Some tissues are more delicate or maybe</p> <p>20 more damaged in a way that if a suture doesn't pass</p> <p>21 through well and it takes sawing back and forth or</p> <p>22 pulling, it might damage the tissue you are trying to</p> <p>23 repair.</p> <p>24 Q. You also said visibility is an important</p> <p>25 characteristic of a surgical suture. Why is that?</p> |

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| <p>38</p> <p>1 A. If you are putting sutures into a<br/>2 structure to fix it and you tie one down and can't<br/>3 really see where it is, you may not know how to place<br/>4 your next suture relative to the first one.<br/>5 Q. In your experience, what makes a surgical<br/>6 suture more visible than another?<br/>7 A. Color.<br/>8 Q. Anything else?<br/>9 A. I think mostly color.<br/>10 Q. Are you familiar with the suture knot<br/>11 configurations identified by number, like a two -- two<br/>12 equals two or three equals two equals one or four<br/>13 equals one equals one? Is that nomenclature -- do you<br/>14 understand that?<br/>15 A. I'm not -- I would answer that by saying<br/>16 I'm not sure. I think I know what you are talking<br/>17 about.<br/>18 Q. What do you think I'm talking about?<br/>19 A. Well, sometimes when people tie knots and<br/>20 they talk about how many half hitches they may place<br/>21 in a knot they may say you put two one way, one<br/>22 another way and two another way and it may be sort of<br/>23 an two-one-two or something.<br/>24 I'm not sure if that's how you are meaning<br/>25 it, but I've seen that before.</p> | <p>40</p> <p>1 you mean by size?<br/>2 A. Diameter.<br/>3 Q. Why is that important?<br/>4 A. Well, if I was to take a shoe string and<br/>5 try to sew your eyelid, that would probably be a<br/>6 problem.<br/>7 Q. Did does that mean the smaller the<br/>8 diameter the better?<br/>9 A. No.<br/>10 Q. Can you explain that then.<br/>11 A. It means that diameter should be<br/>12 appropriate for the location that a suture is being<br/>13 used and the requirements that you are placing on it.<br/>14 Q. For a given procedure, do you have a<br/>15 certain number of half hitches you use when tying a<br/>16 knot?<br/>17 A. No.<br/>18 Q. It varies?<br/>19 A. Yes.<br/>20 Q. It varies on what?<br/>21 A. My per --<br/>22 Q. Go ahead, I'm sorry.<br/>23 A. My perception of how well I've tied the<br/>24 half hitches before, and so I may be doing something<br/>25 that I think I didn't reverse it right or didn't make</p>   |
| <p>39</p> <p>1 Q. In that situation would a knot with less<br/>2 half hitches be considered better than a knot that has<br/>3 more half hitches?<br/>4 A. No.<br/>5 Q. Why not?<br/>6 A. Well, the first important thing we talked<br/>7 about is the security. So, for example, I could throw<br/>8 one half hitch which would be fewer half hitches but<br/>9 that knot won't hold. So fewer is not necessarily<br/>10 better.<br/>11 Q. Assuming that two knots have the same knot<br/>12 security, would the knot with the fewer amount of<br/>13 throws be considered better?<br/>14 A. I don't think I'd necessarily say that.<br/>15 Q. Why not?<br/>16 A. I think the main thing that's important is<br/>17 that the knot holds what it's supposed to hold. I<br/>18 think the extra throw or two is so minor that it's<br/>19 many times hard to know is three enough, is four<br/>20 enough, is five enough? We may say we don't want to<br/>21 take any chances and put one or two more in.<br/>22 So I don't think it's too important<br/>23 whether you do that or not.<br/>24 Q. You also said size was an important<br/>25 characteristic of a surgical suture. First, what do</p>     | <p>41</p> <p>1 it as tight and I want or whatever so I might want to<br/>2 throw more half hitches on it.<br/>3 Q. For a given procedure, what are the ranges<br/>4 of number of half hitches you throw in a knot -- is<br/>5 that right?<br/>6 A. Sure. The number would vary very largely<br/>7 because when we tie arthroscopically we many times use<br/>8 a complex knot as the first knot so it's not just a<br/>9 half hitch. But sometimes you can't do that and so you<br/>10 do have to just use half hitches. So if you are only<br/>11 doing half hitches, obviously, you would throw several<br/>12 on.<br/>13 If you are doing a complex knot, then you<br/>14 may not need as many half hitches to back it up.<br/>15 Q. When you say "complex knot" is that a<br/>16 particular knot or are you just referring to --<br/>17 A. Yes.<br/>18 Q. That's a particular knot configuration?<br/>19 A. Correct.<br/>20 Q. And you've heard the term surgeon's knot?<br/>21 A. Yes.<br/>22 Q. What is a surgeon's knot?<br/>23 A. Well, surgeon's is simply like a half<br/>24 hitch throw only you throw it twice so that you have<br/>25 more friction between the suture when you are trying</p> |

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| <p style="text-align: right;">42</p> <p>1 to apply tension.</p> <p>2 Q. Is that different than a square knot?</p> <p>3 A. Yes.</p> <p>4 Q. What's a square knot?</p> <p>5 A. Describe a square knot. It's an</p> <p>6 over-under-under-over half hitch throw. A surgeon's</p> <p>7 knot is not a knot from the standpoint of a final</p> <p>8 product.</p> <p>9 So a square knot -- when you tie a square</p> <p>10 knot you could argue you have a final product. You are</p> <p>11 not as done. But with a surgeon's throw, all you are</p> <p>12 doing is making it tighter so that you can now throw</p> <p>13 another throw to help finish the knot and lock it in</p> <p>14 place.</p> <p>15 Q. What is a throw?</p> <p>16 A. Like a half hitch.</p> <p>17 Q. What is a half hitch?</p> <p>18 A. It's taking suture and looping it around</p> <p>19 the other limb of the suture.</p> <p>20 Q. Is it similar to tying a shoe, the first</p> <p>21 part of tying a shoe? Do you understand what I'm</p> <p>22 saying?</p> <p>23 A. Yes. Actually, if you are tying a shoe,</p> <p>24 for the first throw if you did it twice and pulled it,</p> <p>25 that's a surgeon's. And so that's what that means.</p>  | <p style="text-align: right;">44</p> <p>1 you have knot security without taking the extra time</p> <p>2 to throw extra half hitches that maybe are not helping</p> <p>3 you.</p> <p>4 Q. So the goal is to secure the knot,</p> <p>5 correct?</p> <p>6 A. Correct.</p> <p>7 Q. What's the disadvantage of throwing ten</p> <p>8 half hitches versus only throwing five half hitches?</p> <p>9 A. My time.</p> <p>10 Q. Anything else?</p> <p>11 A. Patient's time.</p> <p>12 Q. Anything else?</p> <p>13 A. All our time.</p> <p>14 Q. Anything else? Is there a medical reason</p> <p>15 why you wouldn't use ten half hitches or five half</p> <p>16 hitches?</p> <p>17 A. No.</p> <p>18 Q. Does it affect the patient? Does it take</p> <p>19 up real estate in the body?</p> <p>20 A. Well, clearly, if you were talking about</p> <p>21 the entire human body there are places where, clearly,</p> <p>22 taking up real estate could be a problem.</p> <p>23 Q. I'm talking about shoulders.</p> <p>24 A. Right. I don't think there's much that I</p> <p>25 do that that's a big concern. But I think you are</p>   |
| <p style="text-align: right;">43</p> <p>1 So the single throw can be a half hitch</p> <p>2 but, obviously, when you tie your shoe, you lay it</p> <p>3 down a little flatter than what we do when we operate.</p> <p>4 Q. For a given knot, what is the range of</p> <p>5 number of half hitches you throw?</p> <p>6 MR. TAMBURO: Objection, vague.</p> <p>7 A. If I throw a complex knot, then I usually</p> <p>8 put two to four half hitches behind it. If I can't</p> <p>9 throw a complex knot and I'm just throwing half</p> <p>10 hitches, then I probably would be in the six to seven</p> <p>11 range.</p> <p>12 Q. The purposes of the two to four half</p> <p>13 hitches behind the complex knot, is that to hold the</p> <p>14 complex knot?</p> <p>15 A. Correct.</p> <p>16 Q. And then when you just do six to seven</p> <p>17 half hitches that's just -- that's its own that holds</p> <p>18 itself?</p> <p>19 A. Correct.</p> <p>20 Q. Why not do more than six to seven half</p> <p>21 hitches or more than two to four half hitches behind a</p> <p>22 complex knot?</p> <p>23 A. There have been studies done on multiple</p> <p>24 different types of knots and backing it up. And I</p> <p>25 think that that is a reasonable number to be safe that</p> | <p style="text-align: right;">45</p> <p>1 asking why not do ten or 12 and, clearly, you could</p> <p>2 get to the ridiculous and have a rope braided and</p> <p>3 there's no point in that.</p> <p>4 MR. TAMBURO: When you get to a convenient</p> <p>5 point.</p> <p>6 Q. (By Mr. Falke) Does having too many half</p> <p>7 hitches in the body or too many throws in the body</p> <p>8 delay healing of the tissue?</p> <p>9 A. No.</p> <p>10 MR. FALKE: Let's take a break.</p> <p>11 THE VIDEOGRAPHER: Off record, 4:08.</p> <p>12 (Brief recess.)</p> <p>13 THE VIDEOGRAPHER: On the record, 4:21.</p> <p>14 Q. Dr. Burks, in Exhibit 232, paragraph six,</p> <p>15 you state: "I may also describe the specific features</p> <p>16 of FiberWire that I find beneficial in my practice";</p> <p>17 do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Would you describe the specific features</p> <p>20 of FiberWire that you find important?</p> <p>21 A. I think the most important feature is its</p> <p>22 strength, so that it's difficult to break.</p> <p>23 Q. Other than strength, what are the specific</p> <p>24 features of FiberWire that you find beneficial?</p> <p>25 A. Well, I think it provides many of the</p> |

12 (Pages 42 to 45)

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| <p>46</p> <p>1 other features that we talked about that you'd like to<br/>2 see in a suture but it does it in a way that it is a<br/>3 very strong suture which makes it much easier to work<br/>4 with.</p> <p>5 Q. What other features that we talked about<br/>6 apply to FiberWire that you find beneficial?</p> <p>7 A. I guess what I'm meaning is that the<br/>8 features we talked about such a handleability, passing<br/>9 through tissue, knot tying, etc.. I find those<br/>10 features to be good, but what distinguishes it for me<br/>11 primarily is its strength.</p> <p>12 Q. I'm just trying to be specific here. You<br/>13 said handleability, passing through tissue, knot<br/>14 tying, etc. When you say "etc.", what other features<br/>15 that we talked about apply to FiberWire?</p> <p>16 A. I would say all the features that we<br/>17 talked about that you got done writing down. If<br/>18 FiberWire didn't meet those, then its strength might<br/>19 not be important; but since it does meet those and it<br/>20 is stronger than other sutures, then it becomes a<br/>21 preference.</p> <p>22 Q. What suture did you use before FiberWire<br/>23 came onto the market?</p> <p>24 A. For permanent suture we primarily used<br/>25 Ethibond.</p> | <p>48</p> <p>1 Q. Have you ever used OrthoCord?</p> <p>2 A. Yes.</p> <p>3 Q. When have you used Herculine?</p> <p>4 A. Herculine is a Linvitek product and so if<br/>5 I use a Linvitek anchor the Herculine comes with it<br/>6 and so that would usually be the time I'd use it.</p> <p>7 Q. When do you use OrthoCord?</p> <p>8 A. Same thing. OrthoCord is a Mitek product<br/>9 so if I use that I usually get the OrthoCord with it.<br/>10 I sometimes use three strands of OrthoCord when I<br/>11 don't need an anchor and I'm just sewing two tissues<br/>12 together.</p> <p>13 Q. Do you like OrthoCord?</p> <p>14 A. Yes.</p> <p>15 Q. Why do you like OrthoCord?</p> <p>16 A. I think for the same reason I like<br/>17 FiberWire. It's a very strong, hard-to-break suture.</p> <p>18 Q. Does OrthoCord also have the<br/>19 characteristics of good handleability?</p> <p>20 A. Yes.</p> <p>21 Q. Does OrthoCord also have the<br/>22 characteristics of passing through suture well?</p> <p>23 A. Yes.</p> <p>24 Q. Does OrthoCord tie knots well?</p> <p>25 A. Yes.</p>                                   |
| <p>47</p> <p>1 Q. Let me rephrase the question. What suture<br/>2 did FiberWire wire replace in your practice?</p> <p>3 A. It replaced Ethibond.</p> <p>4 Q. Anything else?</p> <p>5 A. Well, there are other companies that make<br/>6 sutures that are like Ethibond. Ethibond is almost<br/>7 like Kleenex where you say Ethibond and you actually<br/>8 might be using a suture from another company but we<br/>9 call it Ethibond. But that's primarily what it<br/>10 replaced.</p> <p>11 Q. Is Ethibond manufactured by Ethicon?</p> <p>12 A. Yes, but due to suture costs and bidding<br/>13 wars, there are other companies that make similar to<br/>14 Ethibond-type suture and we may have used those as<br/>15 well in the past.</p> <p>16 Q. Is FiberWire stronger than Herculine?</p> <p>17 A. I don't know the answer to that.</p> <p>18 Q. Is FiberWire stronger than MaxBraid?</p> <p>19 A. I don't know.</p> <p>20 Q. Is FiberWire stronger than OrthoCord?</p> <p>21 A. I don't know.</p> <p>22 Q. Have you ever used Herculine?</p> <p>23 A. I have.</p> <p>24 Q. Have you ever used MaxBraid?</p> <p>25 A. No.</p>  | <p>49</p> <p>1 Q. Does it have good knot security?</p> <p>2 A. Yes.</p> <p>3 Q. Does it have good knot strength?</p> <p>4 A. Yes.</p> <p>5 Q. If we could turn to paragraph seven,<br/>6 please, in Exhibit 232. Are you there?</p> <p>7 A. I am.</p> <p>8 Q. You state: "I've been using FiberWire<br/>9 suture in my surgical procedures since 2001." What<br/>10 surgical procedures do you use FiberWire in?</p> <p>11 A. I use FiberWire in most of the surgical<br/>12 procedures I do.</p> <p>13 Q. Which ones are they?</p> <p>14 A. I use it with shoulder replacement. I use<br/>15 it with rotator cuff repair. I use it with shoulder<br/>16 instability, knee ligament surgery.</p> <p>17 Q. What knee ligament surgery do you use<br/>18 FiberWire in?</p> <p>19 A. We use FiberWire whenever we want to<br/>20 repair torn ligaments back down to bone.</p> <p>21 Q. You also say in exhibit seven of 232:<br/>22 "Most of my subjective use of FiberWire occurs during<br/>23 surgery and in the surgical environment. FiberWire is<br/>24 generally wet."<br/>25 What do you mean by "subjective use"?</p> |

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| <p style="text-align: right;">50</p> <p>1 A. Poor wording. I guess it was to say that<br/>2 my sense of how FiberWire works and handles, that<br/>3 subjective feel of that is in that environment.<br/>4 Q. So you don't use FiberWire in any<br/>5 non-surgical environment, do you?<br/>6 A. Well, I've used FiberWire in laboratory<br/>7 studies when we do cadaveric studies or other things.<br/>8 But I don't use it for non-medically related things.<br/>9 Q. When you say "most of my subjective use of<br/>10 FiberWire occurs during surgery", were you referring<br/>11 to the surgical environment versus non-surgical<br/>12 environment like you just described?<br/>13 A. Right.<br/>14 Q. Then you say "FiberWire is generally wet<br/>15 in the surgical environment", what does that mean?<br/>16 A. Well, in the environment where I work<br/>17 arthroscopically we work with fluids, so it's hard for<br/>18 a suture not to be wet.<br/>19 Obviously, there are times where we work<br/>20 in a dry air environment and the suture may get wet<br/>21 passing through tissue, but it's not necessarily<br/>22 intentionally wetted like it is with arthroscopy.<br/>23 Q. During surgery, do you wet FiberWire<br/>24 before is it's introduced into the body?<br/>25 A. Not deliberately, no.</p> | <p style="text-align: right;">52</p> <p>1 determines whether you wear gloves?<br/>2 A. In a nonsurgical environment it would be<br/>3 protection for me.<br/>4 Q. Okay. Protection from what?<br/>5 A. Well, if we do cadaveric surgery some<br/>6 cadavers have diseases so we may want to have gloves<br/>7 on when we work with them.<br/>8 Q. What about in the laboratory environment,<br/>9 when you are using FiberWire, do you wear gloves?<br/>10 A. I guess it depends on what you mean by the<br/>11 laboratory environment.<br/>12 Q. By laboratory environment, I mean anything<br/>13 other than a surgical or nonsurgical environment like<br/>14 we've been talking about.<br/>15 A. Well, we do, for example, cadaveric<br/>16 surgery in the laboratory, so we would consider that a<br/>17 laboratory environment, and I would use gloves for<br/>18 self-protection in that setting.<br/>19 Q. Let me ask you a better question. Outside<br/>20 of a surgical environment or nonsurgical environment,<br/>21 do you wear gloves when using FiberWire?<br/>22 A. I guess I would say no.<br/>23 Q. Dr. Burks, if you could turn in Exhibit<br/>24 232 to paragraph eight, you state: "Sometime in<br/>25 February 2006 I was contacted by attorneys for</p> |
| <p style="text-align: right;">51</p> <p>1 Q. Earlier you said the suture may get wet<br/>2 passing through tissue, but it's not necessarily<br/>3 intentionally like it is with arthroscopy. I don't<br/>4 know what that means.<br/>5 A. In an arthroscopic environment we have a<br/>6 microscope in a joint and we distend the joint so we<br/>7 can see with fluid.<br/>8 So any time we introduce suture into that<br/>9 environment it's under water, if you will. So no<br/>10 matter what we do with it, by the time we start to use<br/>11 it, it's wet.<br/>12 Q. When using FiberWire in a surgical<br/>13 environment, do you always wear gloves?<br/>14 A. Yes.<br/>15 Q. What about in the -- let me rephrase the<br/>16 question. In a nonsurgical environment, do you always<br/>17 wear gloves when using FiberWire?<br/>18 A. No.<br/>19 Q. What determines whether you wear gloves?<br/>20 A. Either sterility for a patient or<br/>21 protection for myself.<br/>22 Q. If it's a nonsurgical environment, how<br/>23 does sterility of the patient matter?<br/>24 A. It doesn't.<br/>25 Q. In a nonsurgical environment, what</p>   | <p style="text-align: right;">53</p> <p>1 Arthrex, Inc., and asked to conduct a tactile feel<br/>2 analysis as well as a knot tie-down analysis of coated<br/>3 and uncoated FiberWire suture. I agreed to conduct the<br/>4 analysis." Do you see that?<br/>5 A. I do.<br/>6 Q. Who contacted you in February of 2006?<br/>7 A. Sal Tamburo.<br/>8 Q. Anyone else?<br/>9 A. No.<br/>10 Q. Do you remember the substance of the<br/>11 conversation you had with Sal in February of 2006?<br/>12 A. Yes.<br/>13 Q. What was that substance?<br/>14 A. He said that Arthrex and more, in<br/>15 particular, FiberWire was involved in a patent<br/>16 infringement lawsuit and he was wondering, since I've<br/>17 had experience of using FiberWire, if I would be<br/>18 willing to talk about FiberWire and how its used,<br/>19 etc., and if I'd be willing to look at FiberWire in a<br/>20 couple of different states and give him feedback on<br/>21 what I thought about that.<br/>22 Q. What were those couple different states?<br/>23 A. My understanding was that it was a coated<br/>24 suture and a not-coated suture.<br/>25 Q. Anything else?</p>   |

14 (Pages 50 to 53)

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| <p>54</p> <p>1 A. No.</p> <p>2 Q. Do you know why Sal contacted you as</p> <p>3 opposed to another orthopedic surgeon?</p> <p>4 A. No.</p> <p>5 Q. During the conversation you had with Sal</p> <p>6 in February of 2006, did he suggest that you conduct a</p> <p>7 tactile feel analysis and a knot tie-down analysis?</p> <p>8 A. Yes.</p> <p>9 Q. Did he suggest any other tests to do on</p> <p>10 coated and uncoated FiberWire suture?</p> <p>11 A. No.</p> <p>12 Q. Did you suggest any other test to perform</p> <p>13 at that time, in February of 2006?</p> <p>14 A. No.</p> <p>15 Q. At any time did you suggest doing a test</p> <p>16 other than a knot tie-down or tactile feel analysis</p> <p>17 for purposes of this litigation?</p> <p>18 A. No.</p> <p>19 Q. At any time did anyone suggest to you to</p> <p>20 do a test other than a knot tie-down or tactile feel</p> <p>21 analysis for purposes of this litigation?</p> <p>22 A. No.</p> <p>23 Q. Do you know why they suggested that you</p> <p>24 perform a tactile feel analysis and knot tie-down</p> <p>25 analysis?</p>   | <p>56</p> <p>1 the coated or uncoated samples for purposes of this</p> <p>2 litigation?</p> <p>3 A. No.</p> <p>4 Q. Did Arthrex's attorneys or anyone provide</p> <p>5 you with any documents that helped you render any</p> <p>6 opinions expressed in Exhibit Number 232?</p> <p>7 A. No.</p> <p>8 Q. Did you read any deposition transcripts</p> <p>9 from this case for purposes of rendering your opinions</p> <p>10 in Exhibit Number 232?</p> <p>11 A. The only thing that I had looked at was</p> <p>12 back in paragraph five.</p> <p>13 Q. Dr. Fenton's report?</p> <p>14 A. Yeah, I had seen that but -- I don't</p> <p>15 specifically remember it -- but I had seen it at the</p> <p>16 time.</p> <p>17 Q. How did you see it?</p> <p>18 A. It was sent by Sal.</p> <p>19 Q. Other than Dr. Fenton's report, did you</p> <p>20 receive any other documents from anyone for purposes</p> <p>21 of rendering opinions in this case?</p> <p>22 A. No.</p> <p>23 Q. Prior to performing tests reflected in</p> <p>24 Exhibit Number 232, had you ever performed a tactile</p> <p>25 feel analysis on a coated and uncoated suture before</p> |
| <p>55</p> <p>1 A. Not specifically.</p> <p>2 Q. Generally do you know?</p> <p>3 A. Generally. My general perception is they</p> <p>4 were wanting to determine if the suture seemed</p> <p>5 different with one treatment versus another.</p> <p>6 Q. What do you mean by "seemed different"?</p> <p>7 A. Well, it was a subjective assessment on my</p> <p>8 part if it seemed like the sutures handled differently</p> <p>9 or tied differently.</p> <p>10 Q. Anything else?</p> <p>11 A. No.</p> <p>12 Q. Do you remember anything else from the</p> <p>13 conversation you had with Sal in February of 2006 when</p> <p>14 he called you and asked you to perform these tests?</p> <p>15 A. No.</p> <p>16 Q. So after that conversation, what was the</p> <p>17 scope of your assignment?</p> <p>18 A. I actually told Sal that it would be my</p> <p>19 preference that he send me these two sutures that, you</p> <p>20 know, without specific labeling and that I would then</p> <p>21 work with those two different specimens and call him</p> <p>22 back and say this is what my feelings are.</p> <p>23 Q. Uh-huh. Other than the tactile feel</p> <p>24 analysis and the knot tie-down analysis reported in</p> <p>25 Exhibit 232, did you perform any other tests the on</p> | <p>57</p> <p>1 Arthrex asked you to do it for purposes of this</p> <p>2 litigation?</p> <p>3 A. No.</p> <p>4 Q. Have you ever performed a knot tie-down</p> <p>5 analysis on a coated and uncoated suture before</p> <p>6 Arthrex asked you to do it for purposes of this</p> <p>7 litigation?</p> <p>8 A. No.</p> <p>9 Q. The tactile feel analysis that you</p> <p>10 performed, as reflected in Exhibit 232, is that a</p> <p>11 published test?</p> <p>12 A. No.</p> <p>13 Q. The tactile feel analysis that you</p> <p>14 performed, as reflected in Exhibit 232, was that a</p> <p>15 standard test?</p> <p>16 A. Not that I'm aware of.</p> <p>17 Q. So you are not aware of any publications</p> <p>18 describing the tactile feel analysis that you</p> <p>19 performed in Exhibit Number 232?</p> <p>20 A. No.</p> <p>21 Q. The knot tie-down analysis that you</p> <p>22 performed, as reflected in Exhibit 232, is that a</p> <p>23 published test?</p> <p>24 A. I would say I'm unaware.</p> <p>25 Q. Unaware of what?</p>   |



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| <p>58</p> <p>1 A. Unaware if it's a published test. I'm sure<br/>2 there are some industry standard tests that get done<br/>3 on sutures. but I don't specifically know what those<br/>4 tests are.</p> <p>5 Q. The knot tie-down analysis that you<br/>6 performed, as reflected in Exhibit 232, is that a<br/>7 standard test?</p> <p>8 A. No.</p> <p>9 Q. Have you ever used an uncoated suture<br/>10 during surgery?</p> <p>11 A. I would think I probably have.</p> <p>12 Q. Why do you say that?</p> <p>13 A. I would say over the years we've used an<br/>14 awful lot of different types of sutures, and my best<br/>15 guess would be that there are some that don't have a<br/>16 coating or some other treatment.</p> <p>17 Q. Can you specifically recall ever using an<br/>18 uncoated suture in a surgical environment?</p> <p>19 A. I guess I would answer that by saying I'm<br/>20 uncertain. If we had a list right now of sutures that<br/>21 would be considered uncoated, I probably would say oh,<br/>22 yeah, I've used three or four of those. but I can't<br/>23 give you a specific knowledgeable answer.</p> <p>24 Q. Do you know of any uncoated sutures that<br/>25 are currently on the market?</p> | <p>60</p> <p>1 doesn't mean anything to me.</p> <p>2 Q. Between February of 2006, the initial<br/>3 conversation you had with Sal, and March 2006 when you<br/>4 had the samples, how many conversations did you have<br/>5 with any Arthrex attorney?</p> <p>6 A. Either zero or maybe one to say, hey, the<br/>7 suture is coming and it will be there next week or<br/>8 something.</p> <p>9 Q. You just said when Sal mentioned that<br/>10 there would be somebody in California sending you the<br/>11 sutures, did that happen in the initial conversation<br/>12 or did that happen in a conversation after the initial<br/>13 February 2006 conversation?</p> <p>14 A. In the initial February 2006, I don't<br/>15 think there was a mention of suture being sent. I<br/>16 think it would be a subsequent that the suture was<br/>17 being sent.</p> <p>18 Q. Do you remember anything from the<br/>19 subsequent conversation -- do you remember anything<br/>20 from the conversation after the initial February 2006<br/>21 conversation but before you received the sutures in<br/>22 March of 2006?</p> <p>23 A. Only that there was a conversation about<br/>24 timing of when the suture might get sent or something.</p> <p>25 Q. Did you physically -- what physically did</p> |
| <p>59</p> <p>1 A. I think there may be many sutures that<br/>2 don't have coating.</p> <p>3 Q. Do you know of any uncoated sutures that<br/>4 are currently on the market?</p> <p>5 A. I wouldn't be able to say "I know this is<br/>6 an uncoated suture", no.</p> <p>7 Q. Can you specifically name any uncoated<br/>8 suture that you've used in a surgical environment?</p> <p>9 A. No.</p> <p>10 Q. Moving on to paragraph nine of Exhibit<br/>11 232, you state: "In March 2006 I received two samples<br/>12 of suture labeled suture A and suture B. Each sample<br/>13 was on a spool and was approximately three meters in<br/>14 length." Do you see that?</p> <p>15 A. I do.</p> <p>16 Q. Who sent you the two samples you refer to<br/>17 in paragraph nine of Exhibit 232?</p> <p>18 A. I believe I received them from a company<br/>19 in California.</p> <p>20 Q. Do you know the name of that company?</p> <p>21 A. I don't.</p> <p>22 Q. Does the name CETR mean anything to you?</p> <p>23 A. Only in that -- I think that Sal had<br/>24 mentioned that they had done tests or had been<br/>25 somewhat involved with the suture, but it otherwise</p>   | <p>61</p> <p>1 you receive from the California company when you<br/>2 received the two samples?</p> <p>3 A. I received a plastic bag with a sort of<br/>4 enlarged spool, if you will, that had some suture on<br/>5 it that said sample A and a similar way for one that<br/>6 said sample B.</p> <p>7 Q. Were there two plastic bags each<br/>8 containing one bag of suture?</p> <p>9 A. Yes.</p> <p>10 Q. Anything else?</p> <p>11 A. Packing material.</p> <p>12 Q. What was on the spools?</p> <p>13 A. Just, you know, a length of suture.</p> <p>14 Q. Let me rephrase the question. What<br/>15 markings were on the spools that you received in March<br/>16 2006?</p> <p>17 A. Just sample A, sample B.</p> <p>18 Q. Was that handwritten?</p> <p>19 A. My recollection would be that it was, but<br/>20 I'm not sure.</p> <p>21 Q. Do you know whose handwriting that was?</p> <p>22 A. No.</p> <p>23 Q. Did it say "Pearsalls" on the spool?</p> <p>24 A. I don't remember that.</p> <p>25 Q. Other than sample A and sample B, can you</p>   |

16 (Pages 58 to 61)

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| <p>62</p> <p>1 remember any other marking on the spools?</p> <p>2 A. No.</p> <p>3 Q. Do you know who put the samples on the</p> <p>4 spools that you received in March 2006?</p> <p>5 A. No.</p> <p>6 Q. Could it be that there were other markings</p> <p>7 on the spools other than suture A and suture B?</p> <p>8 MR. TAMBURO: Objection, asked and</p> <p>9 answered.</p> <p>10 A. Certainly there could have been, you know.</p> <p>11 some marking or name. but I don't remember anything</p> <p>12 else that would be pertinent.</p> <p>13 Q. When you received the samples in March</p> <p>14 2006, did you have any indication of whether suture A</p> <p>15 or suture B was coated or uncoated?</p> <p>16 A. No.</p> <p>17 Q. So once you received the samples in the</p> <p>18 two plastic bags on the spools, what did you do next?</p> <p>19 A. Took the suture out, cut the suture with</p> <p>20 just regular scissors to make some lengths, and sort</p> <p>21 of had an A pile and a B pile.</p> <p>22 Q. Where were you when you received the</p> <p>23 suture samples in March of 2006?</p> <p>24 A. I believe they came to my office.</p> <p>25 Q. Did you perform the test in Exhibit 232 at</p> | <p>64</p> <p>1 not told which sample was coated and which was</p> <p>2 uncoated.</p> <p>3 Other than the coated versus uncoated</p> <p>4 distinction, were you told of any other differences</p> <p>5 between the two samples?</p> <p>6 A. No.</p> <p>7 Q. Once you cut the sutures off the spools,</p> <p>8 what did you do with the spools?</p> <p>9 A. Ultimately I pitched them.</p> <p>10 Q. At home?</p> <p>11 A. Uh-huh.</p> <p>12 Q. You threw them away?</p> <p>13 A. Yes.</p> <p>14 Q. What about the plastic bags that were used</p> <p>15 to hold the suture samples?</p> <p>16 A. Same.</p> <p>17 Q. You threw them away?</p> <p>18 A. Uh-huh.</p> <p>19 Q. So you cut five samples from each spool,</p> <p>20 right?</p> <p>21 A. Correct.</p> <p>22 Q. So you had five strands of suture A and</p> <p>23 five strands of suture B each segregated into their</p> <p>24 own pile, right?</p> <p>25 A. Yes.</p>  |
| <p>63</p> <p>1 your office or at home?</p> <p>2 A. I actually did it at home.</p> <p>3 Q. Did you do any tests at the office?</p> <p>4 A. No.</p> <p>5 Q. So you received the samples in the office</p> <p>6 and then brought them home?</p> <p>7 A. Yes.</p> <p>8 Q. Did you cut them at home?</p> <p>9 A. Yes.</p> <p>10 Q. And then after you cut them, how did you</p> <p>11 segregate suture A and suture B?</p> <p>12 A. I just put all the A's from the one spool</p> <p>13 in a single pile and the B's in a separate pile.</p> <p>14 Q. How long were the lengths of suture when</p> <p>15 you cut them off the spool?</p> <p>16 A. They were roughly a couple of feet.</p> <p>17 Q. Was there anybody else present when you</p> <p>18 performed the tests in Exhibit 232?</p> <p>19 A. No.</p> <p>20 Q. Was there anybody else present when you</p> <p>21 cut the samples off the spools?</p> <p>22 A. No.</p> <p>23 Q. It also says in paragraph nine: I was</p> <p>24 told by Arthrex's attorney that one sample was coated</p> <p>25 and that the other sample was uncoated; however, I was</p>   | <p>65</p> <p>1 Q. What did you do next?</p> <p>2 A. I spent a little time taking different</p> <p>3 sutures from one pile or from the other pile and just</p> <p>4 looked at them, felt them, handled them to see if I</p> <p>5 could tell much difference between them.</p> <p>6 Then I put them around a small hook to be</p> <p>7 like a suture anchor environment, if you will, and I</p> <p>8 tied some knots down, some slip knots, to see how it</p> <p>9 would feel.</p> <p>10 Then I wet it, immersed the sutures, and</p> <p>11 tied again to see if I could tell much of a</p> <p>12 difference.</p> <p>13 Q. You said you spent a little time taking</p> <p>14 different sutures from one pile and the other and just</p> <p>15 looked at them, handled them, felt them to see if I</p> <p>16 could tell much difference between them.</p> <p>17 What you just described there, is that the</p> <p>18 tactile feel analysis that you performed as reflected</p> <p>19 in Exhibit 232?</p> <p>20 A. Yes.</p> <p>21 Q. About how long did it take to perform the</p> <p>22 tactile feel analysis as reflected in Exhibit 232 from</p> <p>23 the time you cut the sutures until the time you</p> <p>24 concluded that there was a difference between suture A</p> <p>25 and suture B??</p> |

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| <p style="text-align: right;">66</p> <p>1 A. Ten, 15 minutes.</p> <p>2 Q. About how long did it take to perform the</p> <p>3 knot tie-down analysis as reflected in Exhibit 232</p> <p>4 from the time you cut the sutures off the spools until</p> <p>5 the time you concluded there was a difference between</p> <p>6 suture A and suture B?</p> <p>7 A. Maybe 45 minutes. Can we stop one second?</p> <p>8 MR. FALKE: Sure.</p> <p>9 THE VIDEOGRAPHER: Off the record, 4:52.</p> <p>10 (Discussion off the record.)</p> <p>11 THE VIDEOGRAPHER: On the record, 4:56.</p> <p>12 Q. (By Mr. Falke) Can you please describe the</p> <p>13 tactile field analysis as shown in paragraph 11 of</p> <p>14 Exhibit 232?</p> <p>15 A. Well, it was a very subjective test of</p> <p>16 taking the suture and running it through the</p> <p>17 fingertips and pulling it back and forth. Nothing</p> <p>18 fancy.</p> <p>19 Q. Other than running it through your</p> <p>20 fingertips and pulling it back and forth, did you do</p> <p>21 anything else in the tactile feel analysis?</p> <p>22 A. No.</p> <p>23 Q. How many times did you perform the tactile</p> <p>24 feel analysis in Exhibit 232, paragraph 11?</p> <p>25 A. I'm not sure I could give you a specific</p>   | <p style="text-align: right;">68</p> <p>1 the suture?</p> <p>2 A. I guess I assumed that a coating would</p> <p>3 make it smoother.</p> <p>4 Q. Anything else?</p> <p>5 A. No.</p> <p>6 Q. In the tactile feel analysis, which you</p> <p>7 just described, it sounds like what you described was</p> <p>8 just in the dry environment, is that correct?</p> <p>9 A. That part, yes.</p> <p>10 Q. Did you perform the tactile feel analysis</p> <p>11 in a wet environment as well?</p> <p>12 A. No, it was more knot-tying.</p> <p>13 Q. So you did not test FiberWire in a wet</p> <p>14 environment in the tactile feel analysis in Exhibit</p> <p>15 Number 232?</p> <p>16 A. No.</p> <p>17 Q. But in paragraph 11 it says: "The</p> <p>18 difference between the two samples was even more</p> <p>19 pronounced when they were wet, which is how I'm</p> <p>20 accustomed to using FiberWire"?</p> <p>21 A. Yes. That is, when you are tying knots and</p> <p>22 you are doing it in the wet environment, then you're</p> <p>23 feeling the sutures.</p> <p>24 Q. Right, but if you look at paragraph 11 in</p> <p>25 Exhibit 232, paragraph 11 deals with the tactile feel</p>   |
| <p style="text-align: right;">67</p> <p>1 answer on that from memory. I would say six to eight.</p> <p>2 Q. On each --</p> <p>3 A. On each sample set.</p> <p>4 Q. Okay. On each sample set or on each</p> <p>5 individual suture in the sample?</p> <p>6 A. I did not do each individual suture.</p> <p>7 Q. So you did not actually perform a tactile</p> <p>8 feel analysis on each of the five sutures in suture</p> <p>9 set A and suture set B?</p> <p>10 A. Probably that would be true.</p> <p>11 Q. So then you can't say for sure whether all</p> <p>12 of the five in suture A were generally smoother than</p> <p>13 the five in suture B, is that right?</p> <p>14 A. They all came from the same spool so the</p> <p>15 properties of one strand should be pretty similar to</p> <p>16 the properties of the next strand.</p> <p>17 So the short answer would be yes, I didn't</p> <p>18 compare each strand but the strands I felt would be</p> <p>19 pretty representative coming from the same length.</p> <p>20 Q. You can't say for sure that all the five</p> <p>21 in A were smoother than all five in suture B?</p> <p>22 A. Correct.</p> <p>23 Q. Prior to performing the tactile feel</p> <p>24 analysis in Exhibit 232, did you have any preconceived</p> <p>25 impression of how the coating would affect the feel of</p> | <p style="text-align: right;">69</p> <p>1 analysis, right?</p> <p>2 A. Correct, so what I'm saying on the tactile</p> <p>3 feel analysis is I'm feeling it in a dry environment</p> <p>4 where I'm not doing anything with the suture, just</p> <p>5 feeling it in a dry environment. Then I feel it in</p> <p>6 the wet environment when I'm tying knots.</p> <p>7 Q. So in paragraph eleven when it says "was</p> <p>8 more pronounced when they were wet which is how I'm</p> <p>9 accustomed to using FiberWire" that's not true,</p> <p>10 though, right? You didn't perform --</p> <p>11 A. I think the confusion is maybe how I</p> <p>12 worded this. So when tying knots it's not -- I didn't</p> <p>13 view it personally as being totally separate of</p> <p>14 tactile over here and then a tactile over here.</p> <p>15 When you are tying the knot, you feel the</p> <p>16 suture and you are sliding the knot on it. That was</p> <p>17 part of my assessment when I'm tying the knot. It</p> <p>18 wasn't just laying it out and feeling it. It's a</p> <p>19 combination.</p> <p>20 Q. How do you know that the samples being wet</p> <p>21 was more pronounced in the tactile feel analysis if</p> <p>22 you did not do the tactile feel analysis on a wet</p> <p>23 suture?</p> <p>24 MR. TAMBURO: Objection: asked and</p> <p>25 answered, mischaracterizes the testimony.</p> |

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| <p>70</p> <p>1 A. I'll try to clarify again. I didn't, in my<br/>2 mind, view it as a pure test A/test B. So when you<br/>3 handle suture tying knots and doing things with it,<br/>4 you have a tactile feel. So I didn't -- so that's part<br/>5 of the knot tying. So I didn't segregate it out as two<br/>6 isolated separate things.</p> <p>7 Q. So in your report, Exhibit 232, are you<br/>8 making two conclusions based on a conclusion of the<br/>9 tactile feel analysis and a conclusion based on the<br/>10 knot tie-down analysis?</p> <p>11 A. I'll try to clarify again. A knot tie-down<br/>12 analysis I view as having a tactile aspect to it as<br/>13 well, you are feeling the suture as you tie it. So I<br/>14 don't view them as totally isolated.</p> <p>15 Q. Okay. So how many analyses did you<br/>16 perform as reflected in Exhibit 232?</p> <p>17 A. I used all the strands and tied multiple<br/>18 knots on all the strands. So I'm not, I guess, quite<br/>19 sure -- I can't tell you I did 20 knots on each strand<br/>20 or 30, but they were each used for multiple knot<br/>21 tying.</p> <p>22 Q. My question might have been unclear. Not<br/>23 how many times did you perform the analysis, but how<br/>24 many different analyses did you do in coming to the<br/>25 conclusions as expressed in Exhibit Number 232?</p> | <p>72</p> <p>1 A. I tried to try knots partly with gloves to<br/>2 see if I felt that there was a difference and partly<br/>3 without gloves to see if I could feel a difference.</p> <p>4 Q. Did using gloves in the tests in Exhibit<br/>5 232 affect your ability to distinguish between suture<br/>6 A and suture B?</p> <p>7 A. I think, clearly, using gloves makes the<br/>8 feel of the suture a little different. I guess I can't<br/>9 answer directly to say if it makes the difference but,<br/>10 yes, it probably makes a difference.</p> <p>11 Q. What difference does it make?</p> <p>12 A. You are covering your skin with the<br/>13 gloves, so, you know, as you feel suture, your<br/>14 absolute sensation of the suture probably changes<br/>15 some.</p> <p>16 Q. Could you have reached the same<br/>17 conclusions you reached in Exhibit 232 if you solely<br/>18 used gloves in performing the tests?</p> <p>19 A. I didn't do it that way, so I guess I<br/>20 can't answer that and say yes or no.</p> <p>21 Q. Did not using gloves help you to<br/>22 distinguish between suture A and suture B?</p> <p>23 A. Potentially, yes.</p> <p>24 Q. Did it or -- I'm asking you if, in fact,<br/>25 it did?</p> |
| <p>71</p> <p>1 MR. TAMBURIO: Objection, vague.</p> <p>2 A. I felt the suture and I tied knots with<br/>3 the suture.</p> <p>4 Q. But earlier you testified that that's all<br/>5 encompassed in the knot tie-down analysis. So I'm<br/>6 wondering did you do a knot tie-down analysis and<br/>7 that's it and that had two subparts or two different<br/>8 analyses and then come up with a conclusion -- come up<br/>9 with two different conclusions?</p> <p>10 MR. TAMBURIO: Objection, mischaracterizes<br/>11 the testimony.</p> <p>12 A. Again, I'm not trying to characterize in<br/>13 this that these are segregated separate tests, but<br/>14 this was a tactile feel and knot tying. It was a<br/>15 length subjective feel on both of those.</p> <p>16 So when you tie knots, you get a tactile<br/>17 feel. So I was making the statement that on the<br/>18 tactile feel, how it feels to me, it felt this way and<br/>19 when I tied knots, it also felt that way. It's<br/>20 sometimes hard to do one without doing the other.</p> <p>21 Q. When you were doing -- when you did the<br/>22 tactile feel analysis and the knot tie-down analysis<br/>23 as expressed in Exhibit 232 were you wearing gloves?</p> <p>24 A. Not always.</p> <p>25 Q. Can you explain the breakdown?</p>   | <p>73</p> <p>1 A. And I'm telling you my answer is it<br/>2 potentially did.</p> <p>3 Q. I don't think I understand that. How could<br/>4 it potentially? I mean either it did or didn't,<br/>5 right?</p> <p>6 A. No.</p> <p>7 MR. TAMBURIO: Objection, argumentative.</p> <p>8 Q. Why do you say "potentially"?</p> <p>9 A. I'm trying to be honest. I did feel<br/>10 without gloves and I know there's a pile A and a pile<br/>11 B, so there is potential that feeling suture without<br/>12 gloves made me feel that A was a little different than<br/>13 B that had I been gloved the entire time, I might not<br/>14 have detected.</p> <p>15 Q. So from start to finish then after you cut<br/>16 the suture samples until the time you made your<br/>17 conclusions expressed in Exhibit Number 232, how long<br/>18 was that?</p> <p>19 A. I'll give you the same answer: 45 minutes<br/>20 or so.</p> <p>21 Q. So the 45 minutes encompassed roughly ten<br/>22 minutes you spent on the tactile feel analysis?</p> <p>23 A. No.</p> <p>24 Q. So 45 minutes plus ten minutes or just 45<br/>25 minutes?</p>   |

74

1 A. I would say it was probably 45 minutes  
 2 plus ten minutes.  
 3 Q. Did you tie knots in each of the  
 4 individual five sutures from suture A and suture B?  
 5 MR. TAMBURO: Objection, asked and  
 6 answered.  
 7 A. Yes.  
 8 Q. After you performed the tactile feel  
 9 analysis and knot tie-down, as reflected in Exhibit  
 10 232, what did you do with the sutures that you tested?  
 11 A. I pitched them with the spools.  
 12 Q. You threw them out?  
 13 A. Yes.  
 14 Q. Did counsel ever instruct you to not throw  
 15 away the samples?  
 16 A. No.  
 17 Q. Did counsel give you any instructions at  
 18 all what to do with the samples once you performed the  
 19 tests on them?  
 20 A. No.  
 21 Q. Did you throw them away at home or at the  
 22 office?  
 23 A. At home.  
 24 Q. And then once you completed the tactile  
 25 feel analysis and knot tie-down analysis and once you

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1 threw away the sutures, what did you do next?  
 2 A. Well, as it regards this, I sent an e-mail  
 3 to Sal and said here's what I thought.  
 4 Q. Do you have a copy of that e-mail?  
 5 A. Nope.  
 6 Q. What did you do with the e-mail that you  
 7 sent to Sal after you concluded the tests?  
 8 A. What did I do with the e-mail? I didn't do  
 9 anything with the e-mail. I hit "send".  
 10 Q. It's still on your computer?  
 11 A. I would doubt it's on the computer. I  
 12 mean, just due to the volume, they don't keep three  
 13 months or four months or whatever.  
 14 Q. Did you send it from work or home, the  
 15 e-mail?  
 16 A. I don't know for sure.  
 17 Q. You don't know for sure?  
 18 A. No.  
 19 Q. Did you delete the e-mail you sent to Sal  
 20 after you finished performing the tests?  
 21 A. I'm not sure I understand deleting the  
 22 e-mail. I sent him an e-mail. I didn't purposefully  
 23 delete any e-mail.  
 24 Q. Do you use Microsoft Outlook for your  
 25 e-mails?

76

1 A. No.  
 2 Q. What program do you use for your e-mails?  
 3 A. At home it's a Comcast e-mail and then  
 4 here it's a Group-Wise.  
 5 Q. But do you use -- what e-mailing system do  
 6 you use at home? Is it AOL or Lotus Notes or  
 7 Microsoft Outlook or a Yahoo account?  
 8 A. It's a Comcast.  
 9 Q. That's done on a personal computer?  
 10 A. Yes.  
 11 Q. What about in the office? What kind of  
 12 e-mailing system do you use?  
 13 A. We call it Group-Wise.  
 14 Q. Is the e-mail account you have at home  
 15 different than the one you have at the office?  
 16 A. Uh-huh.  
 17 Q. Did you look for the e-mail in response to  
 18 the subpoena, Exhibit Number 231?  
 19 A. Yes. The e-mail -- I mean, my awareness  
 20 of the e-mails is that they go back two or three weeks  
 21 or so and then after that they just go into  
 22 cyberspace.  
 23 Q. So you did not look for the e-mail in  
 24 response to the subpoena, Exhibit 231?  
 25 A. No, because that was like three months

77

1 ago.  
 2 Q. When you say the e-mails go back two or  
 3 three weeks and then go into cyberspace, you are  
 4 referring to work e-mail or your home e-mail?  
 5 A. Well, primarily, I guess I'm referring to  
 6 the work one. I don't use the home as much. So I  
 7 don't. . .  
 8 Q. Do you remember what the e-mail said that  
 9 you wrote to Sal after you performed the tests in  
 10 Exhibit 232?  
 11 A. Pretty much what's in here. I just said,  
 12 you know, sample A to me felt this way compared to  
 13 sample B.  
 14 Q. Felt -- what word did you use to describe  
 15 how suture A felt in relationship to suture B?  
 16 A. I don't remember specifically but, I mean,  
 17 I probably used a word like "smoother".  
 18 Q. But you are not sure?  
 19 A. I'm not sure of the word.  
 20 Q. Did Sal send an e-mail back to you once  
 21 you sent him the e-mail after completing the tests in  
 22 Exhibit 232?  
 23 A. Not that I remember specifically.  
 24 Q. When was the next time you spoke to Sal  
 25 after sending the e-mail on which you completed the



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| <p style="text-align: right;">78</p> <p>1 tests in Exhibit Number 232?</p> <p>2 A. Oh, boy. I don't remember specifically.</p> <p>3 Q. Do you remember what day you completed the</p> <p>4 tests in Exhibit 232?</p> <p>5 A. No.</p> <p>6 Q. Did you take any notes while doing the</p> <p>7 tests in Exhibit 232?</p> <p>8 A. I did not.</p> <p>9 Q. Do you remember how long -- what the time</p> <p>10 period was between completion of this report and</p> <p>11 completion of the tests?</p> <p>12 A. I don't honestly remember specifically. It</p> <p>13 seems to me that it was a shorter time because of time</p> <p>14 demands on the case.</p> <p>15 Q. Like two weeks or a week?</p> <p>16 A. Yeah. I'll guess in that range. I'm not</p> <p>17 sure.</p> <p>18 Q. So then once you sent the e-mail to Sal</p> <p>19 saying that you completed the tests and giving the</p> <p>20 conclusions you came to, what happened next?</p> <p>21 A. Probably nothing until Sal contacted me</p> <p>22 and said, you know, there's a report that we need to</p> <p>23 do on this, and, you know, we need a CV and we need</p> <p>24 other information and stuff like that.</p> <p>25 Q. What happened next?</p>                         | <p style="text-align: right;">80</p> <p>1 A. I think so.</p> <p>2 Q. And then you made some changes to the</p> <p>3 draft that Sal sent you, right?</p> <p>4 A. Yes.</p> <p>5 Q. And then you sent it back to Sal or you</p> <p>6 had a phone conversation with Sal, is that right?</p> <p>7 A. Yes.</p> <p>8 Q. And then did Sal send you another draft of</p> <p>9 the report after that conversation?</p> <p>10 A. Yeah.</p> <p>11 Q. And then what happened then?</p> <p>12 A. My recollection would be that, you know, I</p> <p>13 called him up and said it seems okay to me, and I</p> <p>14 signed it. And, again, I don't specifically remember</p> <p>15 how he got it back.</p> <p>16 Q. So it sounds like that there was at least</p> <p>17 one initial draft of the report, you made changes to</p> <p>18 it, and then Sal incorporated the changes, he sent it</p> <p>19 back to you, and then you signed off on it; is that</p> <p>20 right?</p> <p>21 A. I think that's fair, yes.</p> <p>22 Q. In paragraph 15 of your report, it says</p> <p>23 that within the past four years you've testified as an</p> <p>24 expert at deposition in one other case; do you see</p> <p>25 that?</p> |
| <p style="text-align: right;">79</p> <p>1 A. We had a couple conversations about what</p> <p>2 would go in the report. He e-mailed a report, it had a</p> <p>3 few blanks, I filled in the blanks and -- you know,</p> <p>4 again, like I said, I don't remember e-mailing or</p> <p>5 whether I picked up the phone or talked to him and had</p> <p>6 completed that part of it and then he sent a final</p> <p>7 draft.</p> <p>8 Q. Okay. You said you had a couple of</p> <p>9 conversations about what would go into the report.</p> <p>10 Do you know how many conversations you had discussing</p> <p>11 what the report would say?</p> <p>12 A. No.</p> <p>13 Q. Do you know how the length -- the total</p> <p>14 length of those conversations about what would go into</p> <p>15 the report?</p> <p>16 A. No. They weren't lengthy.</p> <p>17 Q. An hour?</p> <p>18 A. I don't even think that much.</p> <p>19 Q. Half hour?</p> <p>20 A. Yeah, maybe.</p> <p>21 Q. Then you talked to Sal after you sent him</p> <p>22 the e-mail with your conclusions, you had a couple of</p> <p>23 phone conversations that lasted generally 30 minutes</p> <p>24 and then Sal sent you a draft of the report; is that</p> <p>25 right?</p> | <p style="text-align: right;">81</p> <p>1 A. Yes.</p> <p>2 Q. What case was that?</p> <p>3 A. It was a malpractice case.</p> <p>4 Q. A medical malpractice case?</p> <p>5 A. Yes.</p> <p>6 Q. What role did you serve as an expert in</p> <p>7 that case?</p> <p>8 A. I was giving an opinion for the orthopedic</p> <p>9 surgeon who was being sued in the case.</p> <p>10 Q. The defendant?</p> <p>11 A. Yes.</p> <p>12 Q. Was that Lonnie Paulos?</p> <p>13 A. That was.</p> <p>14 Q. Just generally, can you just describe the</p> <p>15 substance of that opinion? I don't want you to divulge</p> <p>16 any confidentiality, but just --</p> <p>17 A. Well, the substance of the opinion was</p> <p>18 that I didn't feel that he had committed malpractice.</p> <p>19 It was primarily an anesthetic risk case</p> <p>20 and he had been the person operating, so he was</p> <p>21 included in the lawsuit.</p> <p>22 Q. Was Dr. Simon Finger the anesthesiologist?</p> <p>23 A. I'm pretty sure that's correct.</p> <p>24 MR. FALKE: Let's take a break.</p> <p>25 THE VIDEOGRAPHER: Off the record, 5:20.</p>  |

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| <p style="text-align: right;">82</p> <p>1 (Brief recess.)</p> <p>2 THE VIDEOGRAPHER: Back on the record on</p> <p>3 record 5:38.</p> <p>4 Q. (By Mr. Falke) Dr. Burks, can you explain</p> <p>5 the knot tie-down analysis that you conducted as</p> <p>6 reflected in Exhibit 232, paragraph 12?</p> <p>7 A. It was taking a strand, tying a knot on</p> <p>8 it, sliding the knot down and then putting another</p> <p>9 knot/half hitch, whatever you want to describe it, and</p> <p>10 sliding it down.</p> <p>11 Q. What did you tie the suture samples on?</p> <p>12 A. A hook.</p> <p>13 Q. What type of hook was it?</p> <p>14 A. Just a simple sort of brass hook.</p> <p>15 Q. Did you use the same knot configuration</p> <p>16 for each comparison?</p> <p>17 A. I used the same knots for the different</p> <p>18 groups, but I varied knots to see how different knots</p> <p>19 might feel.</p> <p>20 Q. But for each knot that you tied on suture</p> <p>21 B, you did that same knot on suture A?</p> <p>22 A. Right, right.</p> <p>23 Q. About how many knots did you tie in total</p> <p>24 in the know tie-down analysis for each suture set,</p> <p>25 generally?</p>  | <p style="text-align: right;">84</p> <p>1 A. I mean, I took each strand from each set</p> <p>2 and I tied multiple knots, if you will, in each strand</p> <p>3 so each strand may have had 20 throws in it and. . .</p> <p>4 Q. So does that mean then you did five</p> <p>5 comparisons? You did a knot configuration for each of</p> <p>6 the suture samples?</p> <p>7 MR. TAMBURRO: Objection: mischaracterizes</p> <p>8 the testimony, asked and answered.</p> <p>9 A. I guess I'm trying to go with you, I'm</p> <p>10 just not sure what you. . .</p> <p>11 Q. When you say "comparisons", I mean,</p> <p>12 regardless of the knot configurations or how many</p> <p>13 particular knots were on the one suture, you compared</p> <p>14 that configuration, whatever it is, to the other</p> <p>15 suture set, right?</p> <p>16 A. Correct.</p> <p>17 Q. How many times did you do that?</p> <p>18 MR. TAMBURRO: Objection, vague.</p> <p>19 A. I guess one would say that's five. So the</p> <p>20 five strands in one set got compared to the five</p> <p>21 strands in the other set.</p> <p>22 Q. Right. Did you wet the suture when you did</p> <p>23 the knot tie-down analysis?</p> <p>24 A. Yes.</p> <p>25 Q. How did you wet the sutures?</p> |
| <p style="text-align: right;">83</p> <p>1 MR. TAMBURRO: Objection, vague.</p> <p>2 A. When you say suture set, you mean the</p> <p>3 group of sutures or the individual strand?</p> <p>4 Q. The set of five.</p> <p>5 A. Okay.</p> <p>6 Q. So as an example, if you did 30 total</p> <p>7 knots is that 15 per suture A and suture B? Let me</p> <p>8 rephrase the question or repeat the question. About</p> <p>9 how many knots did you tie in total for each suture</p> <p>10 set when you did the knot tie-down analysis?</p> <p>11 A. I think it would be, again, hard to give</p> <p>12 you a specific number. I'm not trying to be vague,</p> <p>13 it's just that when you say a knot, for example, I'm</p> <p>14 trying to say that I might throw a half hitch down</p> <p>15 which isn't technically a complete knot, and then I</p> <p>16 might throw another half hitch, so there might be</p> <p>17 multiple half hitches that you could consider one knot</p> <p>18 or you could consider it 20 throws and 20 knots.</p> <p>19 Q. Let me try to help you out there then. How</p> <p>20 many comparisons then did you do in the knot tie-down</p> <p>21 analysis between suture A and suture B?</p> <p>22 MR. TAMBURRO: Objection, vague.</p> <p>23 Q. Do you understand that?</p> <p>24 A. I can tell you what I did and. . .</p> <p>25 Q. Please.</p> | <p style="text-align: right;">85</p> <p>1 A. With tap water.</p> <p>2 Q. Can you explain that?</p> <p>3 A. Sure, I just filled a glass with water and</p> <p>4 put the suture down in it and then tied the knots.</p> <p>5 Q. Did you wet them one at a time?</p> <p>6 A. Yes.</p> <p>7 Q. How long did the suture stay submerged in</p> <p>8 water?</p> <p>9 A. Briefly. Three or four seconds.</p> <p>10 Q. But the same amount of time in the water</p> <p>11 for each suture?</p> <p>12 A. Yes.</p> <p>13 Q. Do you know if the sutures absorb water</p> <p>14 when they're wet?</p> <p>15 A. No.</p> <p>16 Q. You don't know?</p> <p>17 A. No.</p> <p>18 Q. Were each of the -- you come to the</p> <p>19 conclusion in paragraph number 12 of Exhibit 232 that</p> <p>20 when suture A -- there was less friction when sliding</p> <p>21 the knot on the sample labeled suture A as compared</p> <p>22 with sample labeled B. Was that true for all five</p> <p>23 suture samples?</p> <p>24 A. That was a sum feeling on my part. So it</p> <p>25 might not be fair to say it's true on every strand but</p>   |

22 (Pages 82 to 85)

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| <p style="text-align: right;">86</p> <p>1 it was my overall take from looking at them.</p> <p>2 Q. Do you remember how many -- strike that.</p> <p>3 Does a suture that has less friction when</p> <p>4 sliding that knot mean that the suture has better knot</p> <p>5 tie-down performance?</p> <p>6 A. Not necessarily.</p> <p>7 Q. Why?</p> <p>8 A. Well, if you envision a perfectly smooth</p> <p>9 suture, for example, if you slide a knot it might</p> <p>10 slide very easily but it might also tend to not hold</p> <p>11 as well because there's not as much inherent friction</p> <p>12 in it.</p> <p>13 Q. Does a smoother suture mean it has better</p> <p>14 tactile feel than a suture that is not as smooth?</p> <p>15 A. I would say no, I don't know that I'd say</p> <p>16 it's a better tactile feel.</p> <p>17 Q. Why did you use a surgeon's knot when you</p> <p>18 did the knot tie-down analysis in Exhibit 232?</p> <p>19 A. I think what I would do is say that --</p> <p>20 again, maybe my critique of the verbiage would be at</p> <p>21 fault. So I guess I wouldn't -- you know, we talked</p> <p>22 earlier about what a surgeon's knot is.</p> <p>23 Q. Uh-huh?</p> <p>24 A. And I probably didn't focus on it enough</p> <p>25 to say that they're not necessarily surgeons' knots as</p>        | <p style="text-align: right;">88</p> <p>1 Q. But were there any where you couldn't tell</p> <p>2 a difference? I mean, it was pretty close?</p> <p>3 A. Sure, it was pretty close.</p> <p>4 Q. Let me rephrase. Were there any where you</p> <p>5 couldn't tell the difference between suture A and</p> <p>6 suture B?</p> <p>7 MR. TAMBURO: Objection, asked and</p> <p>8 answered.</p> <p>9 A. I don't remember specifically having ones</p> <p>10 that I would say I clearly feel a difference on this</p> <p>11 one and I clearly don't on the next one. It was a</p> <p>12 general feel of all of them.</p> <p>13 Q. Dr. Burks, how would you describe your</p> <p>14 relationship with Ethicon?</p> <p>15 A. I guess none.</p> <p>16 Q. None? So you would say that you have a</p> <p>17 closer relationship with Arthrex?</p> <p>18 A. Yes.</p> <p>19 Q. What about could you describe your</p> <p>20 relationship with DePuy Mitek?</p> <p>21 A. I have been a consultant with DePuy Mitek.</p> <p>22 Just this week I was helping on an educational course</p> <p>23 for DePuy Mitek reps. But I've had no product or</p> <p>24 anything like that with DePuy Mitek.</p> <p>25 Q. You mean development product work?</p> |
| <p style="text-align: right;">87</p> <p>1 I described them.</p> <p>2 Q. Okay, so why did you use the particular</p> <p>3 knots, then, that you used in the knot tie-down</p> <p>4 analysis?</p> <p>5 A. I just tried to reproduce what I do in the</p> <p>6 operating room.</p> <p>7 Q. In paragraph 11 in Exhibit 232 you state</p> <p>8 that suture A generally felt smoother than suture B.</p> <p>9 What do you mean by "generally"?</p> <p>10 A. The differences between the sutures were</p> <p>11 subtle. I mean, they were not sharp, distinct. So I'm</p> <p>12 meaning that in comparing them, my take was that it</p> <p>13 was generally smoother.</p> <p>14 Q. Were there any of the sutures in the</p> <p>15 tactile feel analysis where you couldn't tell the</p> <p>16 difference between suture A and suture B?</p> <p>17 A. It was not my intent at the time in</p> <p>18 looking at the sutures to compare each strand side to</p> <p>19 side. My intent was to look at sort of spool A and</p> <p>20 spool B. So it was to get a feel of, in general, how</p> <p>21 do they feel between the two.</p> <p>22 So I didn't take a strand and say is this</p> <p>23 one different? And is this one different? And go</p> <p>24 down through that five times, because I felt it was</p> <p>25 all the same suture.</p> | <p style="text-align: right;">89</p> <p>1 A. Yes.</p> <p>2 Q. What was the educational course this last</p> <p>3 week that you helped with DePuy Mitek?</p> <p>4 A. It was educating reps who go into the</p> <p>5 operating room and, you know, are helping surgeons</p> <p>6 with their materials, sutures, implants, what not, and</p> <p>7 how to handle the operating room environment, be</p> <p>8 appropriate and be helpful.</p> <p>9 Q. The course was not on a particular DePuy</p> <p>10 Mitek technique or anything like that, it was --</p> <p>11 A. It was not focused on a particular product</p> <p>12 but it was focused on helping reps better sell DePuy</p> <p>13 Mitek products.</p> <p>14 Q. By being more professional in the</p> <p>15 operating room?</p> <p>16 A. Correct.</p> <p>17 Q. Is this the first time you have done that</p> <p>18 for DePuy Mitek?</p> <p>19 A. This is the second.</p> <p>20 Q. Other than those two courses, have you</p> <p>21 consulted with DePuy Mitek in any other courses?</p> <p>22 A. Yes.</p> <p>23 Q. What are those?</p> <p>24 A. There was an educational course in Chicago</p> <p>25 and you are going to say when and I'm going to guess</p>                  |

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| <p style="text-align: right;">90</p> <p>1 four years ago. It was a cadaver course where they<br/> 2 were doing DePuy Mitek products and they asked me to<br/> 3 come give a couple of talks and help in the lab using<br/> 4 those products with the doctors who were there.<br/> 5 Q. Do you remember what those products were?<br/> 6 A. Not specifically. They were suture<br/> 7 anchors, suture passing instruments, but I don't<br/> 8 remember a specific product.<br/> 9 Q. Are you a consumer of DePuy Mitek<br/> 10 products?<br/> 11 A. Sure.<br/> 12 Q. What DePuy Mitek products do you use?<br/> 13 A. Well, I mentioned earlier I use OrthoCord.<br/> 14 I use some DePuy Mitek anchors. They make an electric<br/> 15 cautery unit that we use. in every case we use<br/> 16 electric cautery.<br/> 17 They have some suture-passing instruments<br/> 18 that we use. I use one of their drill guides and<br/> 19 fixation sets for ACL surgery.<br/> 20 Q. When you do an ACL fixation, what product<br/> 21 do you use?<br/> 22 A. It depends on the type of ACL that we're<br/> 23 doing. If I use a bone/tendon/bone graft which is a<br/> 24 common graft, on the femoral side, I fix it with a<br/> 25 DePuy Mitek device which is a couple of absorbable</p> | <p style="text-align: right;">92</p> <p>1 manufacturing state that those sutures have gone<br/> 2 through. And I'm wondering if you can look at those.<br/> 3 analyze them. do whatever you have to do. but tell me<br/> 4 which ones are coated and which ones are not coated.<br/> 5 if any?<br/> 6 A. So these are three separate types of<br/> 7 suture?<br/> 8 Q. They're three different sutures. Well.<br/> 9 I'm going to take that back. I don't know if they're<br/> 10 three different sutures.<br/> 11 MR. TAMBURIO: You are not sure what they<br/> 12 are.<br/> 13 MR. FALKE: We know what they are. yeah. I<br/> 14 mean, based on Pearsalls' representations of what they<br/> 15 are. If you need to cut them and get you a glass of<br/> 16 water, if you want to wet them.<br/> 17 MR. TAMBURIO: Are they in the same form in<br/> 18 which they were produced?<br/> 19 MR. FALKE: Yes, we did not alter them.<br/> 20 MR. TAMBURIO: Do we have Bates numbers?<br/> 21 Q. Slow down. Just for the record, so the<br/> 22 record is clear, what did you just do, Dr. Burks?<br/> 23 A. I just opened the suture that was in the<br/> 24 bag.<br/> 25 Q. What Exhibit Number is that?</p> |
| <p style="text-align: right;">91</p> <p>1 pins, and on the tibial side I fix it with either a<br/> 2 DePuy Mitek screw or a screw from a different company<br/> 3 depending on upon quality.<br/> 4 On the hamstring, I typically on the<br/> 5 femoral side use a Smith and Nephew product --<br/> 6 Q. EndoButton?<br/> 7 A. EndoButton. On the tibial side I<br/> 8 typically use a Milagro screw and frequently for the<br/> 9 post use that Arthrex screw.<br/> 10 Q. When you say hamstring, that's soft<br/> 11 tissue?<br/> 12 A. Correct.<br/> 13 Q. Semitendonosis?<br/> 14 A. Very good.<br/> 15 MR. TAMBURIO: We're all half doctors here.<br/> 16 MR. FALKE: Let's take a break.<br/> 17 THE VIDEOGRAPHER: Off the record, 5:54.<br/> 18 (Brief recess.)<br/> 19 THE VIDEOGRAPHER: On the record, 6:02.<br/> 20 Q. (By Mr. Falke) Dr. Burks, I'm going to<br/> 21 hand you DePuy Mitek Exhibit 286, DePuy Mitek Exhibit<br/> 22 284 and DePuy Mitek 285. These are FiberWire samples<br/> 23 that were produced to us from Pearsalls who is a<br/> 24 company that makes FiberWire for Arthrex.<br/> 25 I covered up on those exhibits the</p>   | <p style="text-align: right;">93</p> <p>1 A. That is 286.<br/> 2 Q. You cut a piece off of the suture in<br/> 3 Exhibit 286?<br/> 4 A. Right.<br/> 5 Q. And --<br/> 6 MR. TAMBURIO: There's no Bates numbers on<br/> 7 these?<br/> 8 MR. FALKE: There were no Bates numbers.<br/> 9 Q. Would you put that on the suture you cut<br/> 10 from Exhibit 286 and mark with a pen Exhibit 286.<br/> 11 Now, can you explain what you are doing now, Dr.<br/> 12 Burks? First, can you put the suture that you took out<br/> 13 of 286 back in the bag?<br/> 14 A. (Witness complies.)<br/> 15 Q. Thank you, and then proceed. Can you<br/> 16 explain for the record what you are doing now?<br/> 17 A. I'm opening 285.<br/> 18 Q. You are cutting suture sample from Exhibit<br/> 19 285, right?<br/> 20 A. Yes.<br/> 21 Q. Could you please mark with the tape<br/> 22 Exhibit 285 that you've cut? Proceed. Can you state<br/> 23 what for the record what you are doing now?<br/> 24 A. I'm opening number 284.<br/> 25 Q. And cutting a suture from Exhibit 284?</p>  |

24 (Pages 90 to 93)

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| <p style="text-align: right;">94</p> <p>1 A. Yes.</p> <p>2 Q. And now you are going to mark the suture</p> <p>3 sample that you took from Exhibit 284 with a flag?</p> <p>4 A. Correct.</p> <p>5 Q. Can you hand me the original sample sets</p> <p>6 back?</p> <p>7 A. (Witness complies.)</p> <p>8 Q. Also, I'm going to hand you DePuy Mitek</p> <p>9 Exhibit 234 which is a chart I'd like you to fill out</p> <p>10 if you could, please, and under the suture column put</p> <p>11 the numbers corresponding to the suture samples you've</p> <p>12 just cut, just 284, 285 and 286?</p> <p>13 A. Fair enough?</p> <p>14 Q. Fair enough.</p> <p>15 A. Have we got a while?</p> <p>16 Q. However long it takes you.</p> <p>17 MR. TAMBURIO: Are you representing that</p> <p>18 one of them is coated, one of them is not coated?</p> <p>19 MR. FALKE: I'm not making any</p> <p>20 representations. They could all be coated, they could</p> <p>21 all be uncoated, could be a mix?</p> <p>22 A. Can I use your notebook?</p> <p>23 Q. Of course. What do you need?</p> <p>24 A. I was going to use one of those metal</p> <p>25 rings.</p> | <p style="text-align: right;">96</p> <p>1 Q. And 286? Can you explain for the record</p> <p>2 please what you are doing now, Dr. Burks?</p> <p>3 A. I'm tying 284.</p> <p>4 (Discussion off the record.)</p> <p>5 A. Okay. So where is my little sheet here?</p> <p>6 Q. Based on what you've done so far, Dr.</p> <p>7 Burks, can you tell any difference between the</p> <p>8 sutures?</p> <p>9 A. I feel like I do feel a difference.</p> <p>10 Q. Okay. How would you describe that</p> <p>11 difference?</p> <p>12 A. Well, I would say at the moment 285 seems</p> <p>13 a little smoother to me than 284. So I would say 285</p> <p>14 is coated and 284 isn't coated.</p> <p>15 Q. How sure are you of that?</p> <p>16 A. I would not put my children's lives on it,</p> <p>17 but given the subjective feel.</p> <p>18 Q. Is it a subtle difference?</p> <p>19 A. It's a subtle difference.</p> <p>20 Q. Can you explain, Dr. Burks, what you are</p> <p>21 doing now?</p> <p>22 A. Just throwing knots. I would say 286 seems</p> <p>23 coated as well.</p> <p>24 Q. If you had gloves on right now, would that</p> <p>25 change the confidence level you have in determining</p>  |
| <p style="text-align: right;">95</p> <p>1 Q. Sure. First, can you do a tactile feel</p> <p>2 analysis on it? Can you tell the difference?</p> <p>3 A. Kind of -- like I said, when you tie knots</p> <p>4 you combine that together.</p> <p>5 Q. Can you explain what you are doing now?</p> <p>6 A. I don't want to knock your little deal</p> <p>7 off, you know? I'm just getting a sense for how it</p> <p>8 slides and trying to put down a couple of throws.</p> <p>9 Q. Which Exhibit Number are you working on?</p> <p>10 A. I'm on 285.</p> <p>11 Q. Okay. What type of knots are you throwing?</p> <p>12 A. Half hitches.</p> <p>13 Q. Now, can you explain what you are doing,</p> <p>14 Dr. Burks?</p> <p>15 A. Same thing.</p> <p>16 Q. With which exhibit?</p> <p>17 A. 286.</p> <p>18 Q. Are you doing the same thing you did with</p> <p>19 the previous one?</p> <p>20 A. Yes.</p> <p>21 Q. Same knot configurations?</p> <p>22 A. Uh-huh.</p> <p>23 Q. Can you tell a difference between the</p> <p>24 first two sutures, Dr. Burks, Exhibit 285 and --</p> <p>25 A. 286.</p>   | <p style="text-align: right;">97</p> <p>1 whether those are coated or uncoated sutures?</p> <p>2 MR. TAMBURIO: Objection, calls for</p> <p>3 speculation.</p> <p>4 A. I think gloves can make a difference,</p> <p>5 yeah.</p> <p>6 Q. How do they make a difference? The</p> <p>7 difference between the sutures is more subtle, right,</p> <p>8 with gloves because you don't have the contact like</p> <p>9 you described earlier with the skin?</p> <p>10 A. Yeah. Again, this is obviously a very</p> <p>11 subjective feel test. Some of that feel comes from how</p> <p>12 the suture feels and some of it comes from how you</p> <p>13 feel when you slide a knot. So we're not talking rocks</p> <p>14 and water as far as differences and so. . .</p> <p>15 Q. How would you qualify the difference that</p> <p>16 you just observed, based on your test?</p> <p>17 A. When you say "qualify" are you asking for</p> <p>18 like an amount?</p> <p>19 Q. How would you characterize the difference</p> <p>20 between the sutures?</p> <p>21 A. Well the difference is, I think, subtle</p> <p>22 and there's no doubt in my mind that I could line up,</p> <p>23 you know, a hundred sutures and have error where I</p> <p>24 would say, you know, I think this one is one way or</p> <p>25 the other and make a mistake.</p> |



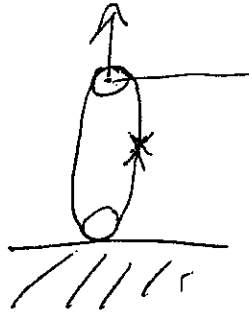
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| <p style="text-align: right;">98</p> <p>1 So there's certainly not enough difference</p> <p>2 to clearly say that I know every time exactly how that</p> <p>3 feels.</p> <p>4 Q. Okay. Could you just initial, please, the</p> <p>5 chart that you did?</p> <p>6 A. This right here?</p> <p>7 Q. Yes.</p> <p>8 A. Okay.</p> <p>9 Q. And put the date.</p> <p>10 A. (Witness complies.)</p> <p>11 Q. Okay. For the record, I have to mark the</p> <p>12 exhibits, the sutures that you tied onto my binder.</p> <p>13 Can you untie those?</p> <p>14 A. I can just open the binder.</p> <p>15 Q. How confident were you that 286 was</p> <p>16 coated?</p> <p>17 MR. TAMBURO: Objection, vague.</p> <p>18 A. I guess I've said that differences are</p> <p>19 subtle. So I'm going by a subjective feel. So I feel</p> <p>20 like there's a difference. Am I going to bet a lot of</p> <p>21 money on it? No, but that's my take.</p> <p>22 MR. FALKE: Okay. For the record I'm</p> <p>23 going to mark the suture that Dr. Burks tested with</p> <p>24 Exhibit 235 -- I'm going to state that over again.</p> <p>25 For the record, I'm going to mark with</p> | <p style="text-align: right;">100</p> <p>1 Deponent's Certificate</p> <p>2</p> <p>3 I, ROBERT T. BURKS, M.D., deponent herein.</p> <p>4 do hereby certify and declare the within and foregoing</p> <p>5 transcription to be my deposition in said action taken</p> <p>6 on June 7, 2006; that I have read, corrected, and do</p> <p>7 hereby affix my signature to said deposition.</p> <p>8</p> <p>9 DATED this ____ day of _____.</p> <p>10 2006.</p> <p>11</p> <p>12 _____</p> <p>13 Deponent</p> <p>14 )</p> <p>14 STATE OF UTAH ) ss.</p> <p>15 )</p> <p>16 SUBSCRIBED AND SWORN to before me this</p> <p>17 ____ day of _____, 2006.</p> <p>18</p> <p>19 _____</p> <p>20 Notary Public residing in</p> <p>21 _____</p> <p>22</p> <p>23 My Commission Expires:</p> <p>24 _____</p> <p>25</p>   |
| <p style="text-align: right;">99</p> <p>1 Exhibit 235 the suture Exhibit 284 that Dr. Burks just</p> <p>2 tested, and I'm going to mark Dr. Burks' tested suture</p> <p>3 286 with DePuy Mitek Exhibit 236, and I'm going to</p> <p>4 mark Dr. Burks' tested suture 285 with DePuy Mitek</p> <p>5 Exhibit 237.</p> <p>6 I have no further questions.</p> <p>7 EXAMINATION</p> <p>8 BY MR. TAMBURO:</p> <p>9 Q. Dr. Burks, there was some discussion about</p> <p>10 work you had performed on behalf of DePuy Mitek; do</p> <p>11 you recall that?</p> <p>12 A. Yes.</p> <p>13 Q. Were you compensated by DePuy Mitek for</p> <p>14 the work you performed?</p> <p>15 A. Yes.</p> <p>16 MR. TAMBURO: I have no further questions.</p> <p>17 MR. FALKE: Okay, thank you for your time.</p> <p>18 THE VIDEOGRAPHER: End of deposition,</p> <p>19 6:18.</p> <p>20 -O-</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>   | <p style="text-align: right;">101</p> <p>1 Reporter's Certificate</p> <p>2 State of Utah )</p> <p>County of Salt Lake )</p> <p>3</p> <p>4 I, Denise Kirk, Certified Shorthand</p> <p>5 Reporter, Registered Professional Reporter, and Notary</p> <p>6 Public for the State of Utah, do hereby certify:</p> <p>7 THAT the foregoing proceedings were taken</p> <p>8 before me at the time and place set forth herein; that</p> <p>9 the witness was duly sworn to tell the truth, the</p> <p>10 whole truth, and nothing but the truth; and that the</p> <p>11 proceedings were taken down by me in shorthand and</p> <p>12 thereafter transcribed into typewriting under my</p> <p>13 direction and supervision;</p> <p>14 THAT the foregoing pages contain a true</p> <p>15 and correct transcription of my said shorthand notes</p> <p>16 so taken.</p> <p>17 IN WITNESS WHEREOF, I have subscribed my</p> <p>18 name and affixed my seal this 11th day of June, 2006.</p> <p>19</p> <p>20 _____</p> <p>21 DENISE KIRK, CSR/RPR</p> <p>22 My commission expires:</p> <p>23 August 30, 2006</p> <p>24</p> <p>25</p> |

# **BROOKSTEIN DECLARATION EXHIBIT 24**

DEPUY MITEK  
EXHIBIT 113  
04cv12457

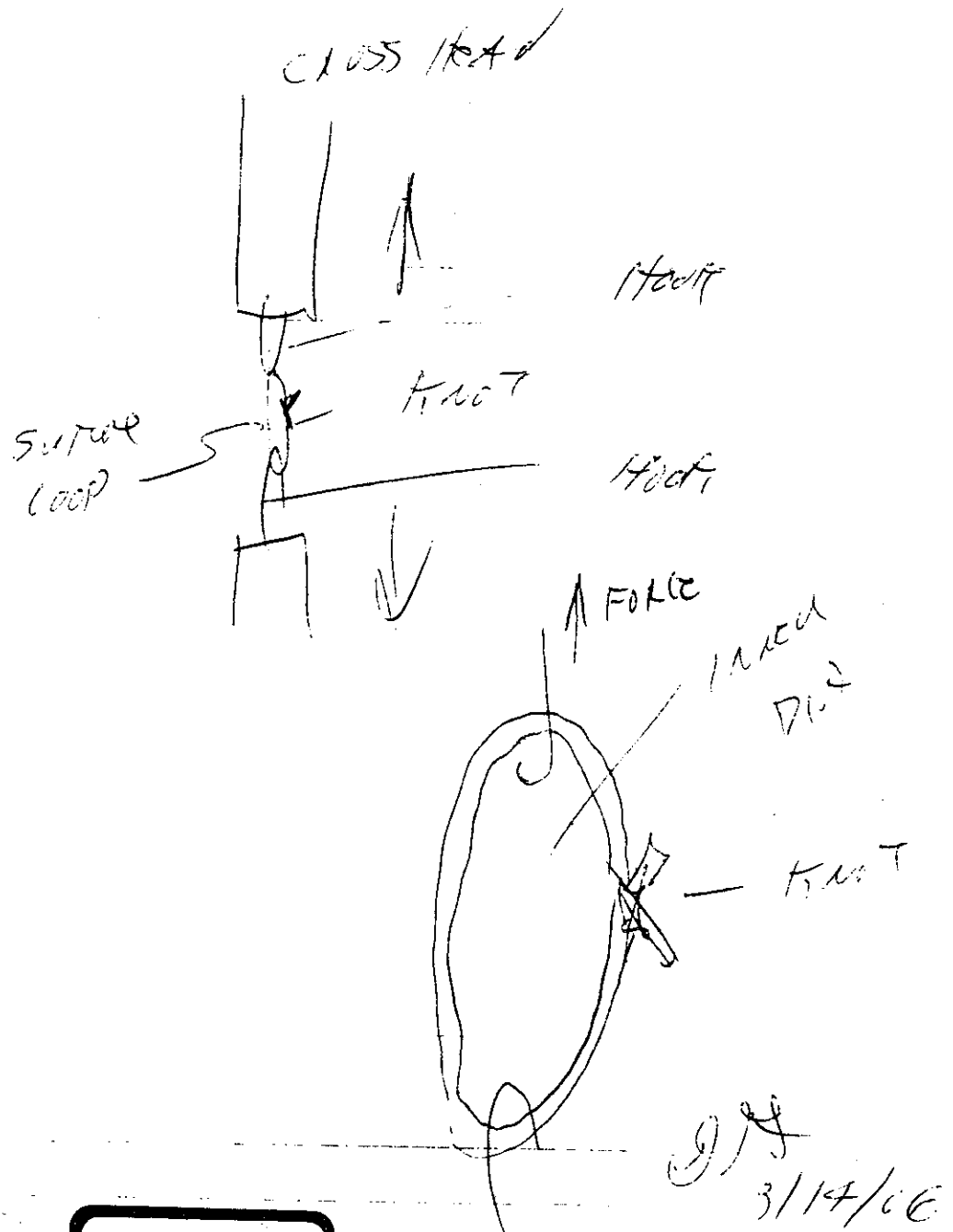
Knot Security

~~Side~~  
Front View



A.H. 09/15/05

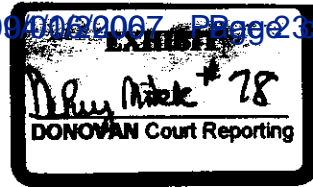
# **BROOKSTEIN DECLARATION EXHIBIT 25**



DEPUY MITEK  
EXHIBIT 421  
04cv12457



# **BROOKSTEIN DECLARATION EXHIBIT 26**



78



February 28, 2001

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation 510(k)  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Re: 510(k) Premarket Notification: Arthrex FiberWIRE™

Dear Ladies and Gentlemen:

This is to notify you of the intention of Arthrex, Inc. to market the above referenced medical device in the United States. We are seeking permission to market the device for the following intended use: general soft tissue approximation, and/or ligation.

This submission is submitted in duplicate and is provided to comply with Section 510(k) Premarket Notification of the Federal Food, Drug and Cosmetic Act in conformance with CFR Title 21, Part 807 Subpart E. This submission includes provisions related to 510(k)'s in the Safe Medical Devices Act of 1990 (SMDA), Public Law 101-629.


Arthrex, Inc. regards the referenced Arthrex FiberWIRE™ to be 'substantially equivalent' as defined for use under the Act to devices of the same type that were in commercial distribution prior to May 28, 1976, or equivalent. The enclosed information addresses the requirements of the Act pertaining to this 510(k) Notification.

We request that the Food and Drug Administration hold as commercial confidential information the intent to market this device for this indication to the fullest extent as authorized by law.

Specific information is submitted as listed in the TABLE OF CONTENTS, Appendix 1 through Appendix 8.

Thank you for your assistance in this matter.

Sincerely,

  
L. Brette Masino  
Regulatory Affairs

CONFIDENTIAL - NON-PATENT  
PROSECUTION COUNSEL  
ONLY

ARM 001888

**Arthrex FiberWIRE™ Braided Polyblend Suture  
Non Absorbable Surgical Suture, USP & EP Conformance**

**Description**

Arthrex FiberWIRE™ is a blend of long chain polyesters braided and sterilized for surgical use. Arthrex FiberWIRE™ is coated with a silica reinforced polydimethylsiloxane. The coating acts as a lubricant for suture sliding and knot tying and ease of passing the suture through tissue.

Arthrex FiberWIRE™ is available in non-dyed (white) or dyed (D & C Blue No. 6) and exceeds USP and EP standards for diameter, knot strength and straight pull strength.

**Indications**

Arthrex FiberWIRE™ is indicated for use in soft tissue approximation and or ligation.

**Actions**

Arthrex FiberWIRE™ elicits minimal acute inflammatory reaction in tissue, as evidenced by in vivo testing. Polyester suture has been shown to become encapsulated by fibrous connective tissue during healing. The polyester suture, Dye (D&C Blue No. 6), and diperoxide silicone oil (coating) are pharmacologically inactive.

**Contraindications**

None Known

**Warnings**

Users should be familiar with surgical procedures and techniques for using non-absorbable suture including wound closure and knot tying.

Do not resterilize. Do not use suture from previously opened or damaged packages.

**Precautions**

Care should be taken when handling braided suture to prevent damage to the individual filaments from abrasion or crimping which could effect the mechanical characteristics of the suture. Do not expose to heat. Assure all knots have been secured using accepted surgical knot tying techniques. Care should be taken to prevent damage to surrounding tissue or user puncture due to improper handling of the needlepoint.

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